OVERWEIGHT AND OBESITY AT 5 YEARS OF AGE IN RELATION TO FRUIT AND VEGETABLE INTAKE OVER TIME

By

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ABSTRACT

Background: Childhood overweight and obesity has increased as American diets have evolved to include fewer fruits and vegetables. It is important to evaluate the effect of dietary components on childhood overweight and obesity.

Objective: To determine if a relationship exists between childhood overweight and obesity and fruit and vegetable intake.

Design: A total of 70 children were followed through 5 years of age in a prospective cohort study. Demographic data, anthropometric measures, and 24-hour dietary recalls were collected. Subjects were grouped by their Body Mass Index (BMI) percentile at age 5 as defined by the Centers for Disease Control and Prevention (CDC) standards. Pearson correlation coefficients were used to determine variables correlating with BMI percentile at five years of age.

Results: Fruit and vegetable intake between 12 months and 5 years of age was not different among 5-year-old children grouped by weight category (healthy, overweight or obese).

Conclusions: Few subjects consumed recommended amounts of fruits and vegetables during the study period therefore, it cannot be ruled out that low fruit and vegetable intake is a factor in overweight and obesity at 5 years of age.

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CHAPTER I

Introduction

Childhood overweight and obesity is a growing problem in the United States (US) and worldwide. Fruits and vegetables are an important part of a healthy diet and may be related to a decrease in risk of overweight and obesity in children. Indisputably, diet patterns have changed to include lower amounts of fruits and vegetables as childhood overweight and obesity has become more prevalent (1).

There are many gaps in the current research regarding the connection of fruit and vegetable intake to childhood overweight and obesity. Few prospective studies exist; those that do have limited populations. The many cross-sectional studies available have conflicting and inconclusive results, possibly due to reverse causation and methodological errors (2). Studies reviewing preschoolers are limited as most articles discuss older child populations. Few studies regarding fruit and vegetable intake and childhood overweight and obesity have demonstrated the expected positive results, and those that have identified positive results are too broad in concept and limited in analysis to draw a concrete conclusion.

Primary Research Question

Does fruit and vegetable intake over time relate to Body Mass Index (BMI) percentile in 5-year-old US children?

Secondary Research Questions

1. How does BMI percentile change over time in 1-5 year old US children?

2. How do demographic variables and caloric intake relate to BMI percentile?

CHAPTER II

Literature Review

Articles were identified for inclusion in this review through a PubMed and CINHL search for studies and reviews looking at childhood obesity and its causes as well as dietary intake of preschoolers and children.

Childhood Overweight and Obesity

Currently the United States (US) assesses childhood weight status using the Center for Disease Control and Prevention's growth charts released in 2000 (3). For children over 2 years of age BMI is calculated by dividing weight in kilograms by height in meters squared. BMI is then plotted on the gender-appropriate growth chart and a BMI-for-age percentile is calculated. Weight status for children under two years of age is determined using weight-for-length percentiles. Based upon the BMI percentile or weight-for length percentile, weight status is classified as underweight (<5th percentile) healthy (5th percentile to 85th percentile), overweight (85th to 95th percentile) or obese (≥ 95th percentile).

During the past several decades Americans of all ages have become increasingly overweight and obese. The increasing prevalence of childhood obesity is concerning because it portends earlier onset of Type 2 Diabetes Mellitus and cardiovascular disease (4, 5) as well as increases the risk of developing many risk factors for chronic disease such as hypertension or abnormal glucose tolerance (6). Obesity prevention and treatment in preschool children is crucial because obesity during early development increases future risk of obesity and comorbidities like Metabolic Syndrome (7).

de Onis et al. (8) report recent obesity prevalence rates by analyzing cross-sectional data from national nutrition surveys of 144 countries. Using the World Health Organization (WHO) Child Growth Standards, global childhood overweight and obesity increased from 4.2% in 1990 to 6.7% in 2010, a relative increase of 60%. Additionally, 14.4% of children aged 0-5 years are at risk for overweight.

Overweight and obesity prevalence rates among young US children are even higher than the above international figures. Ogden et al. (9) examined 2007-2008 data from the National Health and Nutrition Examination Survey (NHANES) and determined that 21.2% of 2-5 year-olds in the US were overweight, with a BMI for age $\geq 85^{th}$ percentile. Of those children, 10.4% were obese with a BMI for age $\geq 95^{th}$ percentile, 6.9% of whom had a BMI $\geq 97^{th}$ percentile (9). The researchers concluded that during 2007-2008 obesity prevalence rates did not appear to be increasing for the population as a whole.

Using NHANES data from 2009-2010 Ogden and colleagues completed another analysis of childhood obesity prevalence in the US. This data showed 26.7% of 2 to 5 year olds were overweight (BMI $\geq 85^{th}$ percentile), 12.1% were obese (BMI $\geq 95^{th}$ percentile) and 7.9% had a BMI $\geq 97^{th}$ percentile. This study also showed an increased prevalence of obesity among male children aged 2 to 19 years and Mexican Americans. In reviewing rates of childhood obesity from 1999-2010 the researchers determined childhood obesity prevalence has remained consistent in this decade across all age groups (10).

Obesity affects many American children, and thus, is an important public health issue. Etiology, prevention, and treatment of childhood overweight and obesity require the attention of researchers in many disciplines including nutrition.

Fruit and Vegetable Recommendations

Fruits and vegetables are an important component of a healthy diet; thus, many governmental and not-for-profit agencies provide intake recommendations to the public. The United States Department of Agriculture (USDA) along with the Department of Health and Human Services (DHHS) revamped the American Food Pyramid in June 2011 to reflect current science-based recommendations for physical activity and dietary intake for each age and gender group based on the 2010 Dietary Guidelines for Americans. The new guidelines recommend children aged 2-3 years consume 1 cup of vegetables and 1 cup of fruit each day while children aged 4-8 should consume 1 to 1.5 cups of fruit and 1.5 cups of vegetables each day (11).

Some non-governmental agencies also provide fruit and vegetable intake recommendations for preventing chronic disease. The American Heart Association (AHA) recommends that all Americans over age 2 consume fresh, frozen or canned fruits and vegetables at every meal for prevention of cardiovascular disease. The AHA cautions against added sauces and sugar on fruit and vegetable dishes and recommends limiting juice intake. According to the AHA children aged 2-8 years should eat 1 to 1.5 servings of both fruits and vegetables every day (12). Similarly, The American Cancer Society recommends

all Americans replace foods and beverages high in calories, fat or refined sugars with fruits and vegetables for cancer prevention (13).

Fruit and Vegetable Intake in the United States

Many researchers have attempted to quantify fruit and vegetable intakes in the United States. NHANES nutrition data are commonly used to assess dietary intake of the US population and are obtained using 24-hour recalls administered by trained interviewers (14). A study using 1999-2002 NHANES data by Lorson et al. (15) shows average daily fruit and vegetable intake for children aged 2-5 years are 1.29 cups and 0.76 cups, respectively. This age group consumes significantly more fruit but few vegetables than older children. The most common fruit and vegetable sources for children are 100% fruit juice and French fries, accounting for 38% of total fruit intake and 28% of total vegetable intake, respectively. Lorson and colleagues estimate 50.2% of 2 to 5-year-olds are not meeting fruit intake recommendations and 78.3% are not meeting vegetable intake recommendations (15).

Another study analyzed NHANES data from 2001-2004 and compared food group intakes to MyPyramid recommendations. Krebs-Smith et al. (14) converted data from 24-hour recalls collected at NHANES exam centers to food groups using the USDA's MyPyramid Equivalents Database. When intakes were compared to MyPyramid recommendations, a majority of the population did not meet recommendations including a high percentage of young children. Children aged 2-3 years had the lowest rates of inadequate fruit intake among all age groups. Dark green vegetables, orange vegetables, legumes, and whole grains

were most likely to be consumed in amounts below intake recommendations. In this analysis, 31.5% of 2-3 year-olds and 62.9% of 4-8 year-olds were estimated to have a usual intake below minimum recommended intakes for total fruit. Similarly, 80.3% of 2-3 year-olds and 92.0% of 4-8 year-olds were estimated to have a usual intake below minimum recommended intakes for total vegetables. At the same time, 99.9% of 2-3 and 4-8 year-olds were estimated to have a usual intake above the maximum discretionary calorie allowance guideline for their sex and age. This high intake of discretionary calories could be displacing fruits and vegetables from the diet, resulting in intakes below recommended levels. Researchers hypothesized this dietary pattern may be related to the high prevalence of overweight and obesity in this population, although no analysis was completed to explore this hypothesis (14).

The Feeding Infants and Toddlers Study (FITS) cohort has also been used to assess dietary intakes of US preschoolers. Children in this cross-sectional study were between 0 and 47 months of age, dietary intake was assessed with one 24-hour recall administered by phone. Data from 24-hour recalls were separated into food groups and fruits and vegetables were analyzed. Estimates of consumption were based solely on fruits and vegetables eaten as separately portioned items. Fruits and vegetables from mixed dishes, like lasagna or soup, were not included. According to Fox et al. (16), 69.7% of 2-3 year-olds consumed a separate portion of vegetables and 87% consumed at least one separate portion of fruit on the day of their recall. Cooked vegetables were more commonly consumed than raw vegetables, and 31% of vegetables eaten were

white potatoes. Whole fresh fruit was the most commonly consumed fruit, and 58.9% of children drank 100% fruit juice. Notably, more children consumed sweetened beverages, deserts, and snack foods than separate portions of vegetables or fruits in a day (16).

As evidenced by the above references, American children consistently consume fewer fruits and vegetables each day than recommended. According to previous research (9-12) this may lead to an increased consumption of high-energy dense foods that lead to weight gain and increase risk for developing chronic disease. It may be especially important to evaluate and encourage fruit and vegetable intakes in young children because dietary habits are formed in early childhood (17).

Fruit and vegetable consumption related to overweight and obesity

Fruit and vegetable consumption is important for overall health and weight control; changes in fruit and vegetable consumption may be related to changes in BMI (1). Dietary patterns in America have changed in the last century to include more energy-dense foods and fewer fruits and vegetables (1). This and other factors are believed contribute to the obesity epidemic in American children.

A limited number of studies have looked at the relation between fruit and vegetable intake and overweight and obesity in preschool children (18-26). Most studies comparing fruit and vegetable intake with overweight and obesity were cross-sectional and all contain limitations affecting generalizability. The studies are grouped here by dietary assessment method. Articles using 3-day food records, 24-hour recalls, and food frequency questionnaires are included.

Three-Day Food Record Analysis

One cross-sectional descriptive study from Turkey analyzed dietary intake of public school children between 6 and 10 years of age with a 3-day food record. The study found obese children consumed an average of 104 kilocalories per day more than non-obese children. Obese children also consumed fewer fruits and vegetables than non-obese children, although both groups consumed insufficient amounts. While this study assesses diet through a more reliable measure than the Food Frequency Questionnaire or a single 24-hour recall, it is limited to Turkish children and its recommendations are based on the USDA Food Pyramid released in 1992. The study also does not adequately control for covariates, omitting parental income which has been shown to correlate with fruit and vegetable intake (27).

Twenty Four-Hour Recall Analysis

Studies using 24-hour recalls for nutrition assessment among the preschool population are limited as well. In a previously referenced study, Lorson et al. (15) showed that overweight children and adolescents consumed less total fruit and more French fries than normal weight children or those at risk for overweight. However, this analysis did not compare intakes by age, sex, or race, which are connected to overweight and obesity (9).

Vernarelli et. al. (28) used data from two NHANES cycles (2001-2002 and 2003-2004) to evaluate the relationship between energy density and measured weight status in children aged 2-8 years. Results show lean children (BMI <85th percentile) in all age groups consumed lower energy-dense diets; and those with

low energy-density diets consumed twice as many fruits and vegetables as those with high energy-density diets.

Food Frequency Questionnaire Analysis

FFQ assess intake over a long period of time, and thus, more accurately represent dietary patterns than a 24-hour recall, which measures intake on a single day. Newby et al. (25) published one of the few prospective studies assessing weight change and dietary intake. In this analysis, fruit and vegetable intake were not related to changes in BMI. While the prospective design of this study minimizes reverse causation, its population of predominately white children from North Dakota limits generalizability to other races and populations.

Similar to the US, increasing rates of childhood overweight and obesity and changes in dietary patterns are also of concern in Korea. Shin et al. (26) assessed dietary patterns and overweight and obesity in Korean preschool children in their cross-sectional study using a food frequency questionnaire. After controlling for confounders, a positive association between health status and a dietary pattern high in vegetable, seaweeds, beans, fruits, and milk and dairy emerged (26). While providing insight into dietary patterns, this study is limited by its subjects' Asian-style diet. Also, the direct correlation between fruit and vegetable intake and childhood overweight and obesity cannot be derived because analysis is based on dietary pattern instead of individual foods or food groups.

Faith et al. (19) report an association between fruit juice intake and adiposity gain in their cross-sectional study of patients at the Supplemental

Program for Women Infants and Children (WIC) in New York state, also using a food frequency questionnaire. Researchers also reported that parental offering of whole fruit was associated with reduced adiposity gain in the at-risk/overweight children of their population (19). The data suggest that replacing energy dense foods with fruits may decrease the risk for overweight and obesity.

Research on fruit and vegetable intake and childhood overweight and obesity is limited by the fact that most studies are cross-sectional and studies have been limited in diversity. Dietary intake is often assessed only once and then compared to longitudinal assessment of BMI.

There is a need for studies that include multiple assessments of dietary intake and BMI assessments on the same child.

CHAPTER III

Materials and Methods

The DIAMOND (DHA Intake And Measurement Of Neural Development) study was a double-blinded, 2-phase, randomized, controlled, parallel-group, prospective trial to observe infants from birth to 18 months of age. The DIAMOND study was designed to determine the effects of infant formula supplemented with long-chain polyunsaturated fatty acids on visual and cognitive development and growth in term infants. The primary objective of the study was to determine visual evoked potential acuity with secondary objectives that examined formula acceptance and tolerance, weight gain, length gain, head circumference gain, fatty acids and vitamin E, stereoacuity, cognitive development, and language development to 18 months of age. After 18 months, children could enroll to follow-up with similar assessment from age two through six years.

Ethics

The follow-up of the study, from two to six years of age, was approved by the Institutional Review Board Ethics Committee and the Human Subjects Committee of the University of Kansas Medical Center in Kansas City, Kansas, as a project (HSC #10205) stemming from the parent trial (HSC #9198): The DIAMOND Study: A Double Masked, Randomized Controlled Clinical Trial of the Maturation of Infant Visual Acuity as a Function of the Dietary Level of Docosahexaenoic Acid. Written informed consent was obtained from each subject's parent(s) or guardian(s) and a copy of the signed written informed

consent form was provided prior to participation in the clinical trial. See Appendices A and B for copies of consent forms from both the original study and the follow-up study. Protected Health Information (PHI) was protected by having all information that could be linked to the subject in a locked file cabinet in a restricted access corridor of Smith West, University of Kansas Medical Center. Only study personnel needing direct access to PHI were allowed access to collected data. All subject records were coded with initials and numbers. No information or data were stored on a laptop or on the internet to prevent identification of subjects. The study was unblinded to the study Principal Investigators (PIs) after all children reached 18 months of age, but personnel with access to subjects did not know their assignment until all children reached six years of age.

Research Setting and Subject Selection

The recruitment and enrollment of study subjects took place in prenatal clinics at two hospitals: Truman Medical Center (TMC) in Kansas City, Missouri, and the University of Kansas Medical Center (KUMC) in Kansas City, Kansas from September 2003 through September 2005. The study was conducted from September 2003 through October 2011.

To be included in the study, infants needed to be healthy, singleton-birth term infants 37 to 42 weeks gestation, weighing between 2490 and 4550 grams at birth, and formula-fed. Infants were excluded if they received human breast milk within 24 hours of randomization or had diseases or abnormalities that could affect growth, development, vision, or cognitive function; or who did not tolerate

cow's milk infant formula or had poor intake of formula. Infants were also excluded if they were born to mothers with HIV, renal disease, hepatic disease, diabetes, substance abuse, or other chronic illnesses or if the family had plans to move out of the Kansas City area within 18 months of enrollment.

Training of Research Staff

The research staff and registered dietitians were trained to measure weight, length, height, and head circumference of infants and children using modules created by the US Department of Health and Human Services (29). Registered dietitians who had been trained to do assessments obtained the measurements.

Staff were trained in conducting 24-hour dietary recalls using the Multiple Pass Method (30). The Multiple Pass Method used for 24-hour dietary recalls collected at the University of Kansas Medical Center consists of first allowing the parent or guardian to list all foods and beverages eaten by the infant and child the day before the clinic visit while the interviewer asks neutral probing questions. Second, the interviewer asks for details about all foods and beverages previously listed including amounts, ingredients and preparation techniques Third, the interviewer reviews the recall with the parent or guardian, probing for missing items (30). All staff members needed to achieve reliability in the Multiple Pass Method before they were allowed to obtain dietary recalls from study subjects.

Research staff and registered dietitians were trained to use Nutrition Data System for Research (NDS-R)® to enter recalls for nutritional analyses. Staff entering dietary recalls into NDS-R® were required to reliably enter 12

standardized 24-hour dietary recalls of hypothetical subjects ranging in age from six weeks to six years with results within five percent of nutrient levels compared to master analyses prior to entering study data.

Data Collection

Data were collected and entered into Microsoft Excel spreadsheets, Microsoft Access databases, and the Nutrition Data System for Research software program by trained research staff and registered dietitians. Anthropometric measures and dietary intakes were assessed at each clinic visit occurring at 6 weeks, 4 months, 6 months, 9 months, 12 months, 18 months, 2 years, 2.5 years, 3 years, 3.5 years, 4 years, 4.5 years, 5 years, 5.5 years, and 6 years. For the purpose of this study only information from clinic visits at 12 months, 18 months, 2 years, 2.5 years, 3 years, 3.5 years, 4 years, 4.5 years, and 5 years will be analyzed.

Demographic Data

Demographic data were collected through interviews and questionnaires. Mothers of infants enrolled in the study reported their education level, race and ethnicity, smoking status prior to and during pregnancy, hours of television viewed by child, and hours of television use at home, as well as other data.

Mothers reported home address at time of enrollment. Income was determined using the subject's enrollment zip code. Average income for enrollment year in the specified zip code was collected from the Mid-America Regional Council's economic database (31). See Appendix C for the Demographic data collection form.

Anthropometric Data

Anthropometric assessments were performed 6 times in year one and twice per year from 12 to 60 months. A length board was used to measure recumbent length, and a stadiometer was used to measure height.

Body weight was recorded to the nearest gram (for infants and children less than 18 months of age) or ounce (2 to 6 years of age) with infants only wearing a dry diaper and children wearing no shoes. Until subjects were two years of age, body length was measured once to the nearest tenth of a centimeter with the subject held in a recumbent position with one person holding the subject's head to contact with the fixed headboard and a second person holding the subject's knees flat and feet with the toes pointing directly upward, while moving the footboard firmly against the subject's heels. Height was measured once using a stadiometer at each visit between two and six years of age with the subject's feet flat on the floor against the wall, looking straight ahead, without shoes. See Appendix D for the anthropometric data collection form.

Anthropometric measures from each clinic visit were used to calculate the Centers for Disease Control growth percentiles using Epi Info software (32-35). Weight and length/height measures were entered into the Epi Info software program to obtain weight-for-length and BMI-for-age percentiles. Epi Info software does not include an age prior to 24 months. At age two, 54 of 79 total subjects were 23 months of age and not exactly 24 months of age by their estimated delivery date (EDD). To accurately calculate the stature-for-age percentiles at age two, the 54 children were rounded to exactly 24 months of age

in Epi Info. Height was not recorded as length and was not recumbent. A t-test comparison of growth percentiles for subjects at 24 months of age and 23 months of age was completed for a prior study (36) and no significant difference was found (p=0.9) between the two groups. Except for stature-for-age, the exact age of the child was used and only the 24-month-old children's data were adjusted.

Dietary Intake Data

Dietary intake was assessed using a 24-hour recall collected from the parent(s) or caregiver(s) by registered dietitians trained by Dr. Debra Sullivan's research team at the University of Kansas Medical Center during each clinic visit. Parents and caregivers have been shown to accurately report dietary intake of preschoolers (37-39). Foods and beverages consumed the day before the clinic visit (i.e. midnight to midnight the day prior) were recorded as well as meal or snack times, portion sizes, and brand names and ingredients used in food preparation. Dietary intake was assessed using descriptions and tools of household measurements including measuring cups and spoons, pre-portioned beanbags of several amounts and sizes, labeled cups, and square, triangle, and circle shapes for sizes of foods. All tools had a reference chart to determine exact amounts. See Appendix E for the 24-hour dietary recall data collection form.

Dietary information from all clinic visits was entered into the Nutrition Data System for Research (NDS-R)® software program (v4.06_34 University of Minnesota, Minneapolis, Minnesota) and exported to NDS-R® version 2010 by a trained registered dietitian. Intake of food groups was reported from NDS-R® by

number of servings reported per day from each dietary recall. See Appendix F for a detailed list of the fruit and vegetable food groups and serving sizes. Recalls that were incomplete or determined to be unreliable were not used, including those missing one or more meals or with kilocalories (kcal) less than 40 kcal per kilogram (kcal/kg) or greater than 200 kcal/kg. See Appendix G for a list of excluded recalls.

Analysis of Data

Income by zip code was calculated as mean ± standard deviation. For analysis, maternal smoking status was classified as never smoked, smoked but not during pregnancy, and smoked during pregnancy.

Calculated weight-for-height and BMI-for-age percentiles were used to categorize subjects as underweight (weight-for-height or BMI-for-age <5%), healthy weight (weight-for-height or BMI-for-age 5-84.9%), overweight (weight-for-height or BMI-for-age 85-94.9%), or obese (weight-for-height or BMI-for-age ≥95%) for each clinic visit (40).

Although the BMI-for-age charts begin at 2 years, only 25 of 79 subjects present for the 2-year clinic visit had BMI-for-age available. For this reason weight-for-height percentiles were used in analysis of subjects between 12 months and 2.5 years of age and BMI-for-age percentiles were used for subjects between 3 and 5 years of age.

Using BMI-for-age percentiles at 5 years of age subjects were then separated into three groups: healthy weight, overweight, or obese based on CDC definitions. These groups were the basis of comparison for further analysis. One

participant had a BMI percentile classified as underweight at the 5-year clinic visit and was not included in the analysis.

NDS-R® Output 9: Food Group Servings at Daily Totals was used to determine fruit and vegetable intake. This output gives a total number of servings consumed of each food group for a particular day. Servings of food groups were transferred into Microsoft Access and then Microsoft Excel, where groups were combined to yield total servings of fruit, total servings of fruit not including fruit juice, total servings of vegetables, and total servings of vegetables not including French fries.

All data points were analyzed with Pearson correlation coefficients using IBM Statistical Package for the Social Sciences (SPSS)® 20.

CHAPTER IV

Results

The first phase of the DIAMOND study enrolled 159 subjects followed from birth to 18 months of age who were evaluated at 6 weeks, 4 months, 6 months, 9 months, 12 months, and 18 months. Children whose parents consented to the DIAMOND follow-up study (phase 2) were followed for growth and developmental outcomes to six years of age and were seen at 2 years, 2.5 years, 3 years, 3.5 years, 4 years, 4.5 years, 5 years, 5.5 years, and 6 years. A total of 70 children were followed from birth to six years of age. Because of the natural break in current literature regarding fruit and vegetable intake this study will evaluate data collected only on clinic visits between 12 months and 5 years of age.

Demographics

Table 1 provides the demographic characteristics of subjects enrolled in the original DIAMOND study and those enrolled through 5 years of age. Race and ethnicity categorized as “Other” represented 2 subjects of other European descent and 2 subjects of unspecified other race or ethnicity.

The original study cohort was 54.1% female, 61.6% African American, 29.6% Caucasian, 6.3% Hispanic, and 2.5% other race or ethnicity. Mean income calculated by zip code was $35,960 and mean maternal years of education was 11.93 years. Seventy subjects were followed through 5 years of age. Of those, a higher proportion were female (70.0%). Race and ethnicity distribution remained similar to the whole cohort with 24.3% Caucasian, 65.7%

African American and 7.1% Hispanic. Mean years of maternal education was the same in both cohorts at 11.97 years; however, mean income was lower in the five-year follow-up group at $33,672.

Table 1: Subject Demographics

	Original Study	5-Year Follow-up
N	159	70
Male [N (%)]	73 (45.9%)	21 (30.0%)
Female [N (%)]	86 (54.1%)	49 (70.0%)
Income by Zip Code [mean ± SD]	$35,960 ± $12,935	$33,672 ± $10,053
Maternal Education [mean years ± SD]	11.93 ± 1.653	11.97 ±1.49
Maternal Race and Ethnicity Caucasian [N (%)]	47 (29.6%)	17 (24.3%)
African American [N (%)]	98 (61.6%)	46 (65.7%)
Hispanic [N (%)]	10 (6.3%)	5 (7.1%)
Other [N (%)]	4 (2.5%)	2 (2.9%)

Table 2 illustrates the demographic differences between BMI category groups. Only one subject's BMI at 5 years of age classified them as underweight and this subject was excluded from analysis. At 5 years of age a majority of subjects (63.8%) were normal weight while 15.9% were overweight and 20.3% were obese.

Table 2: Subject Characteristics by BMI Category at 5 years of age

	Healthy Weight	Overweight	Obese
N	44	11	14
Male [N (%)]	12 (27.3%)	4 (36.4%)	5 (35.7%)
Female [N (%)]	32 (72.7%)	7 (63.6%)	9 (64.3%)
Income by Zip Code[1] [mean ± SD]	$32,995 ± $9,438	$33,429 ± $8,092	$34,220 ± $11,931
Maternal Education [mean years ± SD]	12.00 ± 1.36	10.73 ± 1.19	12.86 ± 1.56
Maternal Race and Ethnicity			
Caucasian [N (%)]	8 (18.2%)	5 (45.5%)	3 (21.4%)
African American [N (%)]	34 (77.3%)	3 (27.3%)	9 (64.3%)
Hispanic [N (%)]	2 (4.5%)	2 (18.2%)	1 (7.1%)
Other [N (%)]	0 (0.0%)	1 (9.1%)	1 (7.1%)

[1] Parental Income

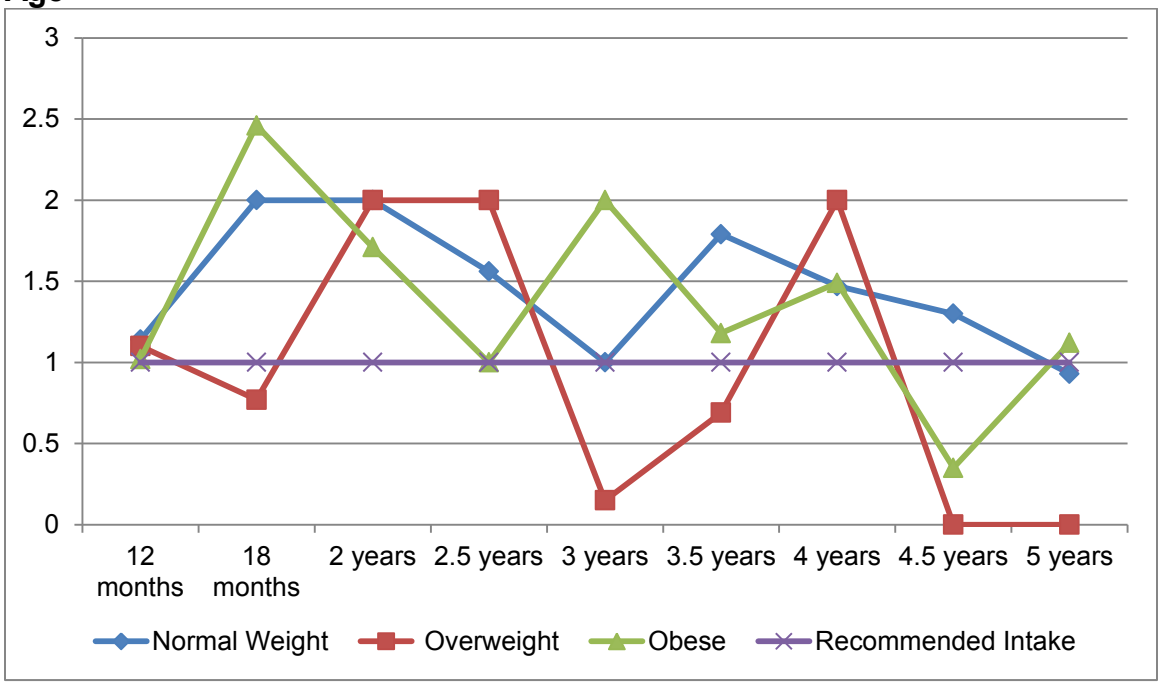
Fruit Intake Over Time Related to BMI at 5 Years of Age

Median total fruit intake, including fruit juice consumption, by BMI group is shown in Table 3 and Figure 1. Minimum fruit intake recorded at all ages and across all BMI groups was zero servings. The USDA recommends children aged 2 to 5 years of age consume at least 1 cup of fruit each day. By this standard the normal weight group met recommendations at all ages except 5 years of age. The overweight group met recommendations at 12 months, 2 years, 2.5 years, and 4 years of age. The obese group met recommendations at all ages between 12 months and 4 years of age.

Table 3: Fruit Intake Over Time by BMI Category at 5 Years of Age

BMI Group	Age	Food	Median	Mean SD	Minimum	Maximum
Healthy Weight	12 months	Total Fruit	1.14	1.29 ± 1.12	0.00	4.66
Overweight		Total Fruit	1.10	1.50 ± 1.70	0.00	5.50
Obese		Total Fruit	1.02	1.55 ± 2.09	0.00	7.38
Healthy Weight	18 months	Total Fruit	2.00	2.10 ± 1.57	0.00	5.51
Overweight		Total Fruit	0.77	1.05 ± 0.91	0.00	2.25
Obese		Total Fruit	2.46	2.06 ± 1.18	0.00	3.61
Healthy Weight	2 years	Total Fruit	2.00	2.18 ± 2.01	0.00	7.94
Overweight		Total Fruit	2.00	1.45 ± 0.94	0.00	6.50
Obese		Total Fruit	1.71	1.73 ± 1.58	0.00	5.50
Healthy Weight	2.5 years	Total Fruit	1.56	2.09 ± 1.89	0.00	6.00
Overweight		Total Fruit	2.00	1.45 ± 0.94	0.00	2.25
Obese		Total Fruit	1.00	2.01 ± 2.32	0.00	6.50
Healthy Weight	3 years	Total Fruit	1.00	1.67 ± 1.84	0.00	6.11
Overweight		Total Fruit	0.15	0.39 ± 0.47	0.00	1.00
Obese		Total Fruit	2.00	1.61 ± 1.74	0.00	5.23
Healthy Weight	3.5 years	Total Fruit	1.79	1.83 ± 1.33	0.00	4.00
Overweight		Total Fruit	0.69	0.56 ± 0.47	0.00	1.00
Obese		Total Fruit	1.18	1.60 ± 1.84	0.00	5.25
Healthy Weight	4 years	Total Fruit	1.47	1.38 ± 1.47	0.00	5.44
Overweight		Total Fruit	2.00	2.05 ± 2.21	0.00	5.58
Obese		Total Fruit	1.49	1.45 ± 1.53	0.00	4.50
Healthy Weight	4.5 years	Total Fruit	1.30	1.74 ± 2.19	0.00	9.74
Overweight		Total Fruit	0.00	0.52 ± 0.77	0.00	2.00
Obese		Total Fruit	0.35	0.62 ± 0.75	0.00	2.00
Healthy Weight	5 years	Total Fruit	0.93	1.19 ± 1.5	0.00	6.00
Overweight		Total Fruit	0.00	0.63 ± 1.17	0.00	3.00
Obese		Total Fruit	1.12	1.25 ± 1.43	0.00	4.11

Figure 1: Median Total Fruit Intake Over Time by BMI Category at 5 Years of Age

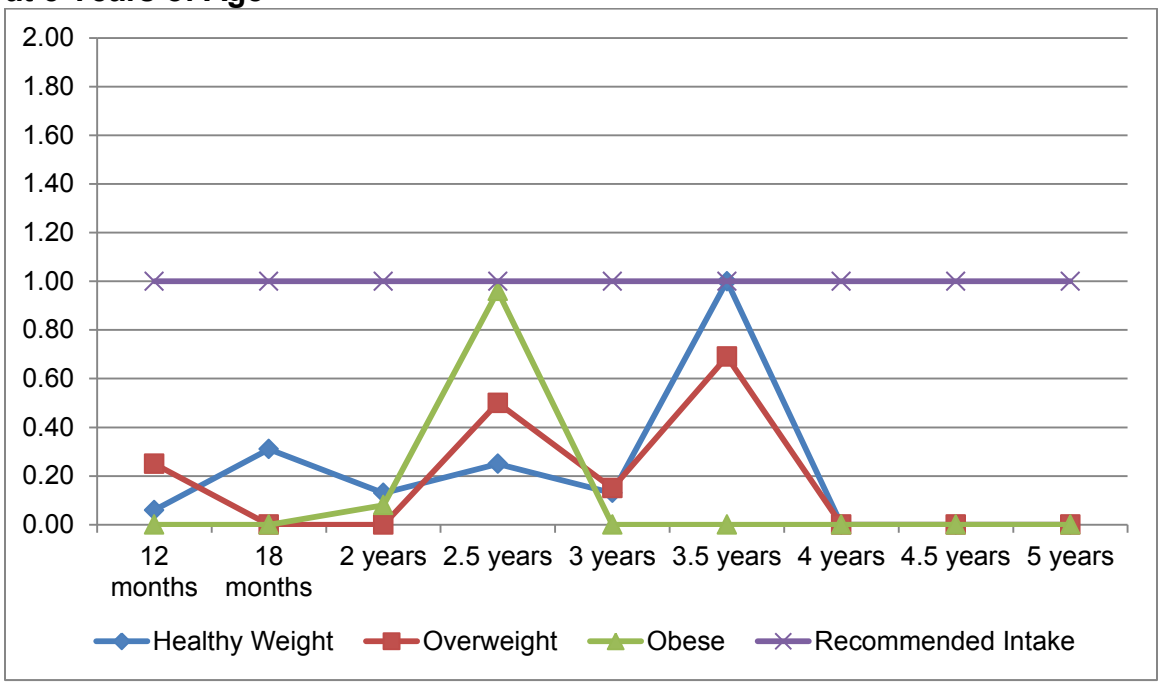


However, fruit intake recommendations were met only once across all ages and BMI groups when excluding juice intake, as seen in Table 4 and Figure 2. The healthy weight group met recommendations for fruit intake when excluding juice only at 3.5 years of age with a median intake of 1.00 serving. At no age did the overweight group meet fruit intake recommendations when excluding juice intake. The obese group never met fruit intake recommendations when excluding juice intake although intake was near recommendation at 2.5 years of age (median 0.96 servings).

Table 4: Fruit Intake Excluding Juice Over Time by BMI Group

BMI Group	Age	Food	Median	Mean ± SD	Minimum	Maximum
Healthy Weight	12 months	Fruit, No Juice	0.06	0.47 ± 0.74	0.00	3.28
Overweight		Fruit, No Juice	0.25	0.70 ± 0.94	0.00	2.82
Obese		Fruit, No Juice	0.00	0.45 ± 0.69	0.00	1.94
Healthy Weight	18 months	Fruit, No Juice	0.31	0.73 ± 1.01	0.00	4.00
Overweight		Fruit, No Juice	0.00	0.27 ± 0.37	0.00	0.86
Obese		Fruit, No Juice	0.00	0.60 ± 0.92	0.00	3.08
Healthy Weight	2 years	Fruit, No Juice	0.13	0.51 ± 0.71	0.00	3.00
Overweight		Fruit, No Juice	0.00	0.71 ± 1.19	0.00	3.76
Obese		Fruit, No Juice	0.08	0.26 ± 0.34	0.00	1.02
Healthy Weight	2.5 years	Fruit, No Juice	0.25	0.79 ± 1.17	0.00	4.00
Overweight		Fruit, No Juice	0.50	0.70 ± 0.84	0.00	2.00
Obese		Fruit, No Juice	0.96	0.79 ± 0.75	0.00	2.00
Healthy Weight	3 years	Fruit, No Juice	0.13	0.59 ± 0.71	0.00	2.00
Overweight		Fruit, No Juice	0.15	0.39 ± 0.47	0.00	1.00
Obese		Fruit, No Juice	0.00	0.57 ± 0.76	0.00	2.00
Healthy Weight	3.5 years	Fruit, No Juice	1.00	0.93 ± 0.96	0.00	4.00
Overweight		Fruit, No Juice	0.69	0.56 ± 0.47	0.00	1.00
Obese		Fruit, No Juice	0.00	0.59 ± 0.88	0.00	2.21
Healthy Weight	4 years	Fruit, No Juice	0.00	0.59 ± 0.86	0.00	2.94
Overweight		Fruit, No Juice	0.00	0.48 ± 0.68	0.00	1.75
Obese		Fruit, No Juice	0.00	0.57 ± 0.84	0.00	2.08
Healthy Weight	4.5 years	Fruit, No Juice	0.00	0.68 ± 1.27	0.00	5.74
Overweight		Fruit, No Juice	0.00	0.24 ± 0.41	0.00	1.00
Obese		Fruit, No Juice	0.00	0.29 ± 0.49	0.00	1.00
Healthy Weight	5 years	Fruit, No Juice	0.00	0.56 ± 1.20	0.00	6.00
Overweight		Fruit, No Juice	0.00	0.35 ± 0.60	0.00	1.42
Obese		Fruit, No Juice	0.00	0.37 ± 0.51	0.00	1.00

Figure 2: Median Fruit Intake Excluding Juice Over Time by BMI Category at 5 Years of Age



As seen in Table 5 total fruit intake at 3.5 years of age was negatively correlated to BMI in the group that was overweight at 5 years of age (p=0.04). No other significant correlations were found between BMI group and fruit intake.

Table 5: Fruit Intake Over Time Correlated to BMI Category at 5 Years of Age

Food	Age		Healthy Weight	Overweight	Obese
Fruit No Juice	12 months	r	-0.05	0.11	-0.04
		P	0.7	0.38	0.77
Total Fruit		r	-0.08	0.38	0.77
		P	0.52	0.78	0.62
Fruit No Juice	18 months	r	0.13	-0.16	-0.03
		P	0.32	0.22	0.85
Total Fruit		r	0.14	-0.25	0.04
		P	0.3	0.05	0.77
Fruit No Juice	2 years	r	0.01	0.13	-0.15
		P	0.94	0.34	0.27
Total Fruit		r	-0.05	0.17	-0.12
		P	0.73	0.20	0.37
Fruit No Juice	2.5 years	r	0.04	-0.02	0.01
		P	0.81	0.88	0.93
Total Fruit		r	0.08	-0.10	0.00
		P	0.57	0.50	0.98
Fruit No Juice	3 years	r	0.03	-0.09	0.00
		P	0.82	0.54	0.99
Total Fruit		r	0.03	-0.22	-0.01
		P	0.86	0.12	0.96
Fruit No Juice	3.5 years	r	0.17	-0.11	-0.12
		P	0.24	0.43	0.40
Total Fruit		r	0.21	-0.29	-0.01
		P	0.15	0.04*	0.92
Fruit No Juice	4 years	r	0.06	-0.04	0.01
		P	0.69	0.76	0.97
Total Fruit		r	-0.07	0.15	0.00
		P	0.62	0.29	0.99
Fruit No Juice	4.5 years	r	0.17	-0.13	-0.11
		P	0.28	0.40	0.48
Total Fruit		r	0.29	-0.19	-0.17
		P	0.06	0.21	0.28
Fruit No Juice	5 years	r	0.11	-0.06	-0.05
		P	0.49	0.72	0.75
Total Fruit		r	0.10	-0.14	0.06
		P	0.52	0.36	0.71

r Pearson's Correlation Coefficient
P P-value

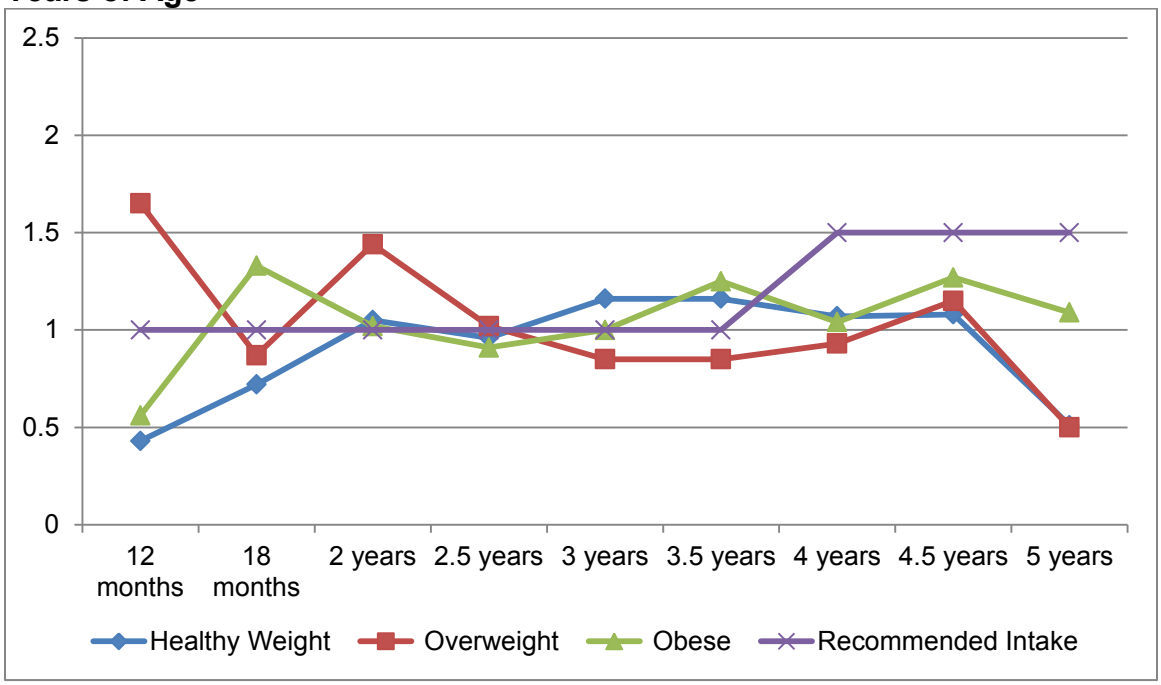
Vegetable Intake Over Time Related to BMI at 5 Year

Total vegetable intake over time is reported in Table 6 and Figure 3. The USDA recommends children aged 2 to 3 years consume 1 cup of vegetables each day while children aged 4-8 years should consume 1.5 cups of vegetables each day. The normal weight group met vegetable intake recommendations at 2 years, 3 years, and 3.5 years, of age. The overweight group met recommendations at 12 months, 2 years, and 2.5 years of age. The obese group met vegetable intake recommendations at 18 months, 2 years, 3 years, and 3.5 years of age.

Table 6: Total Vegetable Intake Over Time by BMI Category at 5 Years of Age

BMI Group	Age	Food	Median	Mean ± SD	Minimum	Maximum
Healthy Weight	12 months	Total Veg	0.43	0.62 ± 0.84	0.00	4.42
Overweight		Total Veg	1.65	1.45 ± 1.02	0.00	3.21
Obese		Total Veg	0.56	1.38 ± 1.89	0.00	6.46
Healthy Weight	18 months	Total Veg	0.72	1.06 ± 0.95	0.04	4.25
Overweight		Total Veg	0.87	1.03 ± 0.99	0.00	3.07
Obese		Total Veg	1.33	1.33 ± 1.02	0.00	2.86
Healthy Weight	2 years	Total Veg	1.05	1.16 ± 0.79	0.00	2.98
Overweight		Total Veg	1.44	1.49 ± 0.79	0.13	2.55
Obese		Total Veg	1.02	1.74 ± 2.02	0.00	6.53
Healthy Weight	2.5 years	Total Veg	0.96	1.22 ± 1.05	0.00	4.10
Overweight		Total Veg	1.02	0.81 ± 0.75	0.00	1.63
Obese		Total Veg	0.91	1.05 ± 0.75	0.00	2.23
Healthy Weight	3 years	Total Veg	1.16	1.27 ± 0.88	0.00	3.74
Overweight		Total Veg	0.85	0.96 ± 0.78	0.00	2.16
Obese		Total Veg	1.00	1.34 ± 0.88	0.30	3.06
Healthy Weight	3.5 years	Total Veg	1.16	1.51 ± 1.36	0.00	6.33
Overweight		Total Veg	0.85	0.78 ± 0.60	0.00	1.45
Obese		Total Veg	1.25	1.09 ± 0.76	0.00	2.08
Healthy Weight	4 years	Total Veg	1.07	1.44 ± 1.12	0.00	4.00
Overweight		Total Veg	0.93	0.92 ± 0.47	0.02	1.52
Obese		Total Veg	1.04	1.05 ± 0.76	0.13	2.06
Healthy Weight	4.5 years	Total Veg	1.08	1.43 ± 1.52	0.00	6.26
Overweight		Total Veg	1.15	1.14 ± 0.74	0.00	2.10
Obese		Total Veg	1.27	1.48 ± 1.17	0.00	3.40
Healthy Weight	5 years	Total Veg	0.51	0.99 ± 1.42	0.00	5.47
Overweight		Total Veg	0.50	0.64 ± 0.72	0.00	1.90
Obese		Total Veg	1.09	1.17 ± 0.88	0.14	3.07

Figure 3: Median Total Vegetable Intake Over Time by by BMI Category at 5 Years of Age

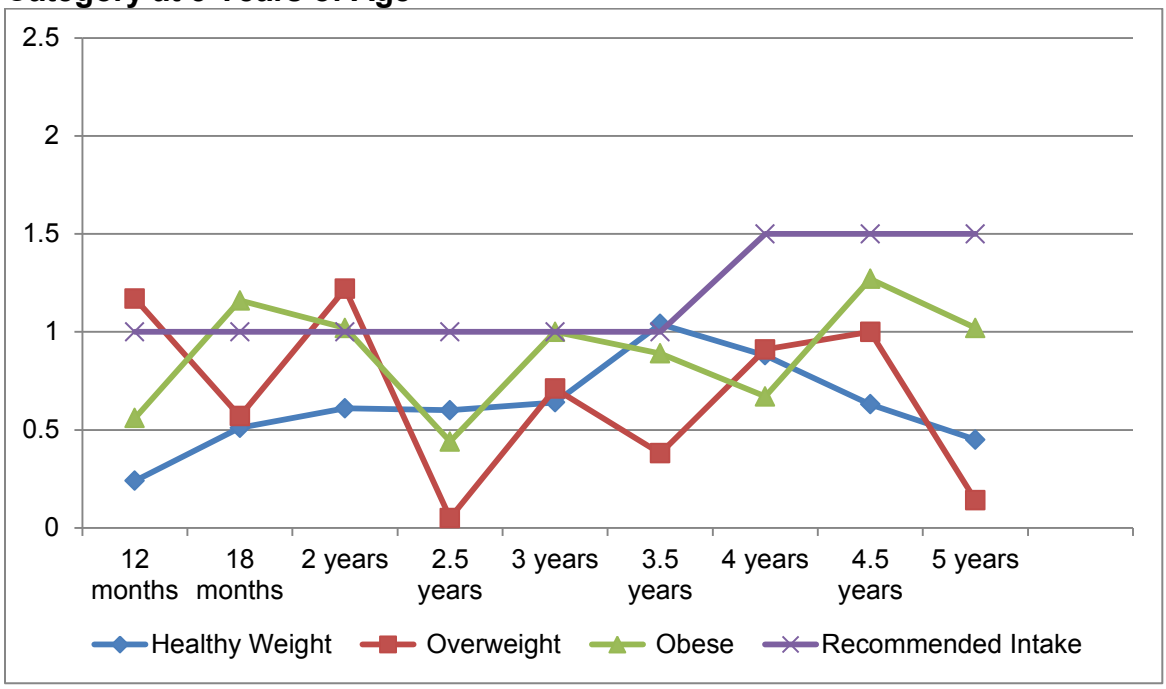


Only at 3.5 years of age did vegetable intake meet recommendations when excluding French fries in the normal weight group as seen in Table 7 and Figure 4. At 12 months and 2 years of age vegetable intake excluding French fries met recommendations in the overweight group. At 18 months, 3 years and 3.5 years of age vegetable intake excluding French fries met recommendations in the obese group.

Table 7: Vegetable Intake Excluding French Fries Over Time by BMI Category at 5 Years of Age

BMI Group	Age	Food	Median	Mean ± SD	Minimum	Maximum
Healthy Weight	12 months	Veg, No FF	0.24	0.48 ± 0.77	0.00	4.42
Overweight		Veg, No FF	1.17	1.07 ± 0.87	0.00	2.24
Obese		Veg, No FF	0.56	1.31 ± 1.92	0.00	6.46
Healthy Weight	18 months	Veg, No FF	0.51	0.85 ± 0.99	0.00	3.89
Overweight		Veg, No FF	0.57	0.90 ± 0.98	0.00	3.07
Obese		Veg, No FF	1.16	1.12 ± 1.09	0.00	2.86
Healthy Weight	2 years	Veg, No FF	0.61	0.83 ± 0.76	0.00	2.55
Overweight		Veg, No FF	1.22	1.18 ± 0.87	0.00	2.47
Obese		Veg, No FF	1.02	1.50 ± 1.93	0.00	6.53
Healthy Weight	2.5 years	Veg, No FF	0.60	0.96 ± 1.00	0.00	4.10
Overweight		Veg, No FF	0.05	0.39 ± 0.70	0.00	1.63
Obese		Veg, No FF	0.44	0.69 ± 0.68	0.00	1.91
Healthy Weight	3 years	Veg, No FF	0.64	0.93 ± 0.82	0.00	2.90
Overweight		Veg, No FF	0.71	0.62 ± 0.54	0.00	1.19
Obese		Veg, No FF	1.00	1.30 ± 0.91	0.30	3.06
Healthy Weight	3.5 years	Veg, No FF	1.04	1.36 ± 1.29	0.00	6.33
Overweight		Veg, No FF	0.38	0.58 ± 0.61	0.00	1.45
Obese		Veg, No FF	0.89	0.85 ± 0.74	0.00	1.75
Healthy Weight	4 years	Veg, No FF	0.88	1.15 ± 1.09	0.00	4.00
Overweight		Veg, No FF	0.91	0.78 ± 0.58	0.00	1.52
Obese		Veg, No FF	0.67	0.81 ± 0.71	0.13	2.06
Healthy Weight	4.5 years	Veg, No FF	0.63	1.25 ± 1.58	0.00	6.26
Overweight		Veg, No FF	1.00	1.04 ± 0.73	0.00	2.10
Obese		Veg, No FF	1.27	1.36 ± 1.16	0.00	3.40
Healthy Weight	5 years	Veg, No FF	0.45	0.90 ± 1.32	0.00	4.99
Overweight		Veg, No FF	0.14	0.45 ± 0.69	0.00	1.90
Obese		Veg, No FF	1.02	0.80 ± 0.40	0.14	1.18

Figure 4: Vegetable Intake Excluding French Fries Over Time by BMI Category at 5 Years of Age



Correlations between vegetable intake over time and BMI percentile at 5 years of age are shown in Table 8. Healthy weight BMI percentile at 5 years of age was negatively correlated with total vegetable intake and vegetable intake excluding French fries at 12 months of age (p=0.01, 0.01). Obese BMI percentile was positively correlated to vegetable intake excluding French fries at 12 months of age (p=0.04). No other significant correlations were found between vegetable intake and BMI percentile at 5 years of age.

Table 8: Vegetable Intake Over Time Correlated to BMI Percentile at 5 Years of Age

Food	Age		Healthy Weight	Overweight	Obese
Total Veg	12 months	r	-0.32	0.19	0.21
		P	0.01*	0.12	0.10
Veg no FF		r	-0.31	0.12	0.26
		P	0.01*	0.34	0.04*
Total Veg	18 months	r	-0.06	-0.03	0.12
		P	0.63	0.81	0.37
Veg no FF		r	-0.08	0.00	0.11
		P	0.53	0.99	0.41
Total Veg	2 years	r	-0.20	0.07	0.18
		P	0.14	0.59	0.19
Veg no FF		r	-0.23	0.07	0.21
		P	0.09	0.58	0.11
Total Veg	2.5 years	r	0.15	-0.11	-0.04
		P	0.30	0.44	0.78
Veg no FF		r	0.20	-0.16	-0.08
		P	0.16	0.26	0.59
Total Veg	3 years	r	0.03	-0.11	0.06
		P	0.85	0.43	0.70
Veg no FF		r	-0.09	-0.15	0.21
		P	0.51	0.29	0.15
Total Veg	3.5 years	r	0.23	-0.16	-0.09
		P	0.10	0.25	0.55
Veg no FF		r	0.26	-0.18	-0.12
		P	0.06	0.20	0.42
Total Veg	4 years	r	0.22	-0.15	-0.10
		P	0.12	0.31	0.49
Veg no FF		r	0.18	-0.10	-0.10
		P	0.20	0.47	0.48
Total Veg	4.5 years	r	0.03	-0.09	0.03
		P	0.86	0.57	0.87
Veg no FF		r	0.00	-0.07	0.04
		P	1.00	0.66	0.82
Total Veg	5 years	r	0.04	-0.12	0.09
		P	0.82	0.46	0.59
Veg no FF		r	0.12	-0.14	0.00
		P	0.46	0.37	1.00

r Pearson's Correlation Coefficient
P P-value

BMI Over Time

Table 9 below illustrates the change in BMI percentile over time for all subjects and for subjects followed in Phase II of the study from 2 through 5 years of age.

Table 9: BMI Percentile Categories Over Time by Cohort

Cohort	Age	Underweight	Healthy Weight	Overweight	Obese
Whole Cohort (N=103)	12 months	6 (5.8%)	76 (73.8%)	15 (14.6%)	6 (5.8%)
Phase II (N=70)		4 (5.7%)	51 (72.9%)	11 (15.7%)	4 (5.7%)
Whole Cohort (N=90)	18 months	5 (5.6%)	67 (74.4%)	13 (14.4%)	5 (5.6%)
Phase II (N=68)		5 (7.4%)	49 (72.1%)	10 (14.7%)	4 (5.9%)
Whole Cohort (N=79)	2 years	4 (5.1%)	64 (81.0%)	6 (7.6%)	5 (6.3%)
Phase II (N=67)		4 (6.0%)	52 (77.6%)	6 (9.0%)	5 (7.5%)
Whole Cohort (N=75	2.5 years	8 (10.7%)	54 (72.0%)	8 (10.7%)	5 (6.7%)
Phase II (N=66)		6 (9.1%)	47 (71.2%)	8 (12.1%)	5 (7.6%)
Whole Cohort (N=76)	3 years	8 (10.5%)	56 (73.7%)	5 (6.6%)	7 (9.2%)
Phase II (N=69)		7 (10.1%)	50 (72.5%)	5 (7.2%)	7 (10.1%)
Whole Cohort (N=77)	3.5 years	1 (1.3%)	54 (70.1%)	14 (18.2%)	8 (10.4%)
Phase II (N=68)		1 (1.5%)	47 (69.1%)	12 (17.6%)	8 (11.8%)
Whole Cohort (N=77)	4 years	3 (3.9%)	45 (58.4%)	18 (23.4%)	11 (14.3%)
Phase II (N=69)		2 (2.9%)	39 (56.5%)	18 (26.1%)	10 (14.5%)
Whole Cohort (N=71)	4.5 years	2 (2.8%)	42 (59.2%)	12 (16.9%)	15 (21.1%)
Phase II (N=68)		2 (2.9%)	39 (57.4%)	12 (17.6%)	15 (22.1%)
Whole Cohort (N=70)	5 years	1 (1.4%)	44 (62.9%)	11 (15.7%)	14 (20.0%)
Phase II (N=70)		1 (1.4%)	44 (62.9%)	11 (15.7%)	14 (20.0%)

Table 10 shows the distribution of BMI category over time among BMI groups. As depicted in Figures 5-7, the most dramatic changes occur beginning at 3 years of age when more subjects move to the overweight and obese BMI categories. While subjects in all BMI groups appear to change weight statuses over time the weight status of the BMI groups from 12 months through 3 years of age changed little. After three years of age the overweight and obese weight classes become proportionately larger compared to the normal weight class.

Table 10: BMI Change Over Time by BMI Category at 5 years of age

BMI Group at 5 years	Age	BMI Category							
		Underweight		Healthy Weight		Overweight		Obese	
Normal Weight (N=44)	12 months	4	(9.1%)	34	(77.3%)	5	(11.4%)	1	(2.3%)
Overweight (N=11)		0	(0.0%)	7	(63.6%)	3	(27.3%)	1	(9.1%)
Obese (N=14)		0	(0.0%)	9	(64.3%)	3	(21.4%)	2	(14.3%)
Normal Weight (N=42)	18 months	5	(11.9%)	33	(78.6%)	3	(7.1%)	1	(2.4%)
Overweight (N=11)		0	(0.0%)	6	(54.5%)	5	(45.5%)	0	(0.0%)
Obese (N=14)		0	(0.0%)	9	(64.3%)	2	(14.3%)	3	(21.4%)
Normal Weight (N=41)	2 years	4	(9.8%)	36	(87.8%)	1	(2.4%)	0	(0.0%)
Overweight (N=11)		0	(0.0%)	8	(72.7%)	1	(9.1%)	2	(18.2%)
Obese (N=14)		0	(0.0%)	7	(50.0%)	4	(28.6%)	3	(21.4%)
Normal Weight (N=40)	2.5 years	5	(12.5%)	33	(82.5%)	2	(5.0%)	0	(0.0%)
Overweight (N=11)		0	(0.0%)	8	(72.7%)	1	(9.1%)	2	(18.2%)
Obese (N=14)		0	(0.0%)	6	(42.9%)	5	(35.7%)	3	(21.4%)
Normal Weight (N=43)	3 years	6	(14.0%)	35	(81.4%)	1	(2.3%)	1	(2.3%)
Overweight (N=11)		0	(0.0%)	9	(81.8%)	1	(9.1%)	1	(9.1%)
Obese (N=14)		0	(0.0%)	6	(42.9%)	3	(21.4%)	5	(35.7%)
Normal Weight (N=42)	3.5 years	1	(2.4%)	38	(90.5%)	2	(4.8%)	1	(2.4%)
Overweight (N=11)		0	(0.0%)	7	(63.6%)	4	(36.4%)	0	(0.0%)
Obese (N=14)		0	(0.0%)	1	(7.1%)	6	(42.9%)	7	(50.0%)
Normal Weight (N=43)	4 years	2	(4.7%)	35	(81.4%)	5	(11.6%)	1	(2.3%)
Overweight (N=11)		0	(0.0%)	2	(18.2%)	7	(63.6%)	2	(18.2%)
Obese (N=14)		0	(0.0%)	1	(7.1%)	6	(42.9%)	7	(50.0%)
Normal Weight (N=42)	4.5 years	1	(2.4%)	37	(88.1%)	3	(7.1%)	1	(2.4%)
Overweight (N=11)		0	(0.0%)	2	(18.2%)	7	(63.6%)	2	(18.2%)
Obese (N=14)		0	(0.0%)	0	(0.0%)	2	(14.3%)	12	(85.7%)
Normal Weight (N=44)	5 years	0	(0.0%)	44	(100.0%)	0	(0.0%)	0	(0.0%)
Overweight (N=11)		0	(0.0%)	0	(0.0%)	11	(100.0%)	0	(0.0%)
Obese (N=14)		0	(0.0%)	0	(0.0%)	0	(0.0%)	14	(100.0%)

Figure 5: Percent of Healthy Weight Subjects Over Time by BMI Group

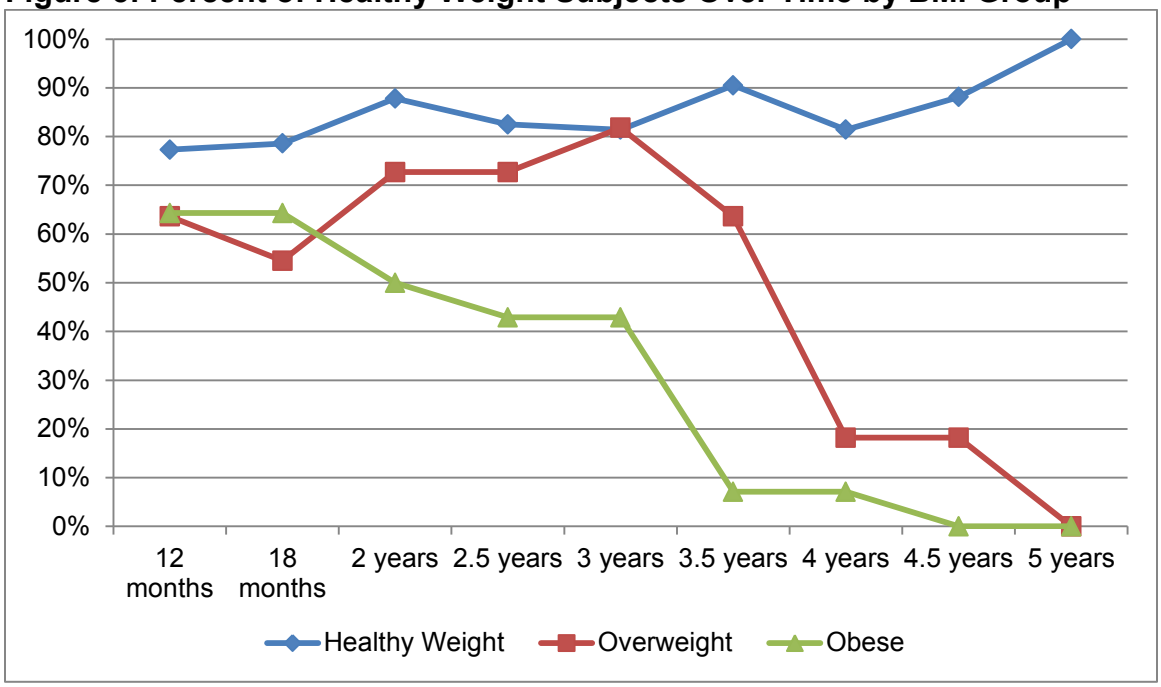


Figure 6: Percent of Overweight Subjects Over Time by BMI Group

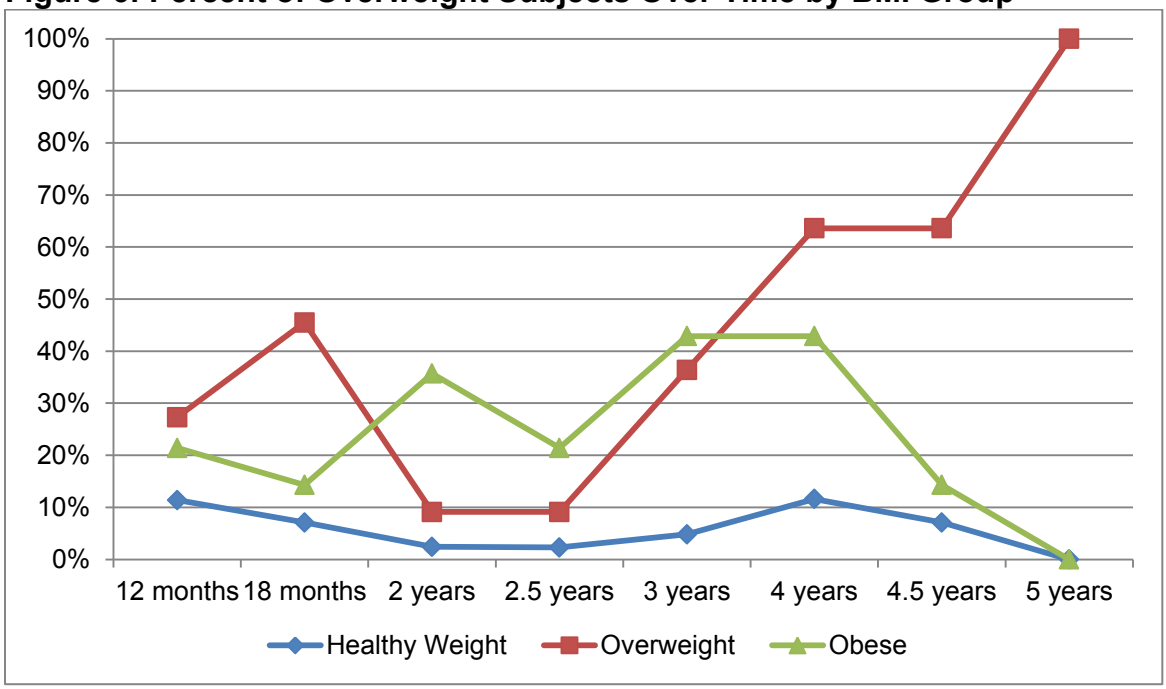
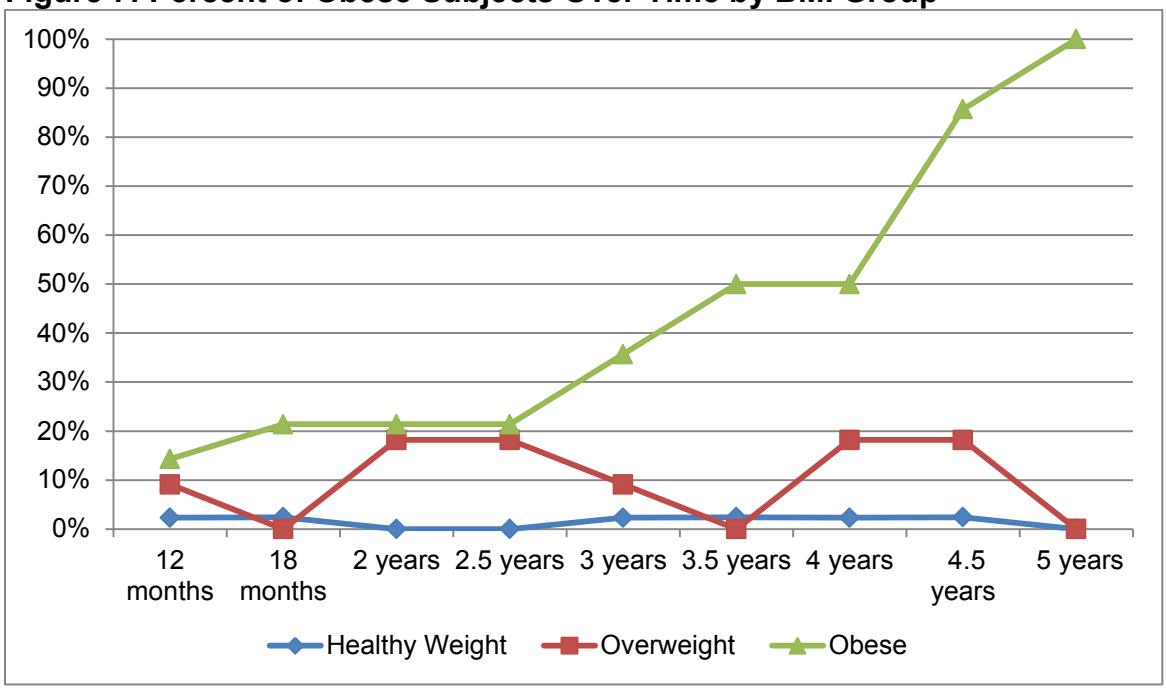


Figure 7: Percent of Obese Subjects Over Time by BMI Group



Other Factors Related to Fruit and Vegetable Intake and BMI Percentile

Income and Maternal Years of Education

Income calculated by enrollment zip code appears to be associated with fruit intake as shown in Table 11. Income by zip code was positively correlated with fruit intake excluding juice at 18 months (p=0.04) and 2 years of age (p=0.01). Total fruit intake at 2 years of age (p=0.00) and 3 years of age (p=0.05) Only one significant correlation was identified between income by zip code and BMI percentile classification.

Table 11: Income by Zip Code Related to Fruit Intake in All Subjects

Age	Food	Pearson Correlation Coefficient (r)	2-tailed Significance (P)
12 months	Fruit, No Juice	0.04	0.67
(N=103)	Total Fruit	-0.11	0.27
18 months	Fruit, No Juice	0.24	0.04*
(N=87)	Total Fruit	0.07	0.58
2 years	Fruit, No Juice	0.34	0.01**
(N=77)	Total Fruit	0.34	0.00**
2.5 years	Fruit, No Juice	-0.18	0.14
(N=71)	Total Fruit	0.04	0.76
3 years	Fruit, No Juice	-0.02	0.85
(N=70)	Total Fruit	0.24	0.05*
3.5 years	Fruit, No Juice	-0.16	0.19
(N=75)	Total Fruit	0.00	0.99
4 years	Fruit, No Juice	0.10	0.41
(N=76)	Total Fruit	0.12	0.31
4.5 years	Fruit, No Juice	-0.09	0.48
(N=72)	Total Fruit	0.06	0.63
5 years	Fruit, No Juice	-0.05	0.68
(N=70)	Total Fruit	0.01	0.96

Although maternal years of education were positively correlated to income by zip code (p=0.018) no significant correlations between maternal years of education and fruit and vegetable intake were identified. However, maternal years of education was positively correlated to obese BMI percentile classification at 3.5 years of age (p=0.003), 4.5 years of age, (p=0.005) and 5 years of age (p=0.012) as well as overweight BMI percentile classification at 5 years of age (p=0.002). See Table 12.

Table 12: Maternal Years of Education Related to BMI Percentile Over Time in All subjects

Age	BMI Group	Pearson Correlation Coefficient (r)	2-tailed Significance (P)
12 months (N=103)	Healthy Weight	0.01	0.95
	Overweight	-0.03	0.78
	Obese	-0.02	0.83
18 months (N=87)	Healthy Weight	0.04	0.75
	Overweight	-0.12	0.28
	Obese	0.17	0.12
2 years (N=77)	Healthy Weight	-0.09	0.46
	Overweight	0.13	0.27
	Obese	0.00	1.00
2.5 years (N=71)	Healthy Weight	-0.04	0.72
	Overweight	0.13	0.28
	Obese	-0.03	0.83
3 years (N=70)	Healthy Weight	-0.09	0.47
	Overweight	-0.01	0.95
	Obese	0.18	0.13
3.5 years (N=75)	Healthy Weight	-0.18	0.11
	Overweight	-0.04	0.71
	Obese	0.39*	0.00
4 years (N=76)	Healthy Weight	-0.12	0.30
	Overweight	0.00	0.99
	Obese	0.17	0.15
4.5 years (N=72)	Healthy Weight	-0.12	0.31
	Overweight	-0.20	0.10
	Obese	0.33*	0.01
5 years (N=70)	Healthy Weight	0.03	0.84
	Overweight	-0.36*	0.00
	Obese	0.30*	0.01

Race and Ethnicity

BMI percentile related to race and ethnicity is shown in Tables 13-15. Hispanic ethnicity was positively correlated to obese BMI percentile at 12 months of age (p=0.007) and 4 years of age (p=0.002) as well as overweight BMI percentile at 3.5 years of age (p=0.002) and negatively correlated with normal weight BMI percentile at 3.5 years of age (p=0.043). Other unspecified race or ethnicity was positively correlated with overweight BMI percentile at 18 months of age (p=0.014), 4.5 years of age (p=0.026), and 5 years of age (p=0.019). African

American race was negatively correlated with obese BMI percentile at 2.5 years of age (p=0.042) as well as overweight BMI percentile at 5 years of age (p=0.003) and positively correlated to normal weight BMI at 5 years of age (p=0.008). Other European race was positively correlated with overweight BMI percentile at 3 years of age (p<0.001) and 3.5 years of age (p=0.033) as well as obese BMI percentile at 4 years of age (p=0.013) and 5 years of age (p=0.045).

Table 13: Race and Ethnicity Correlated to Healthy Weight BMI Percentile Over Time in All Subjects

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	0.06	-0.06	0.02	0.01	0.06	0.09	0.07	0.19	0.32*
P	0.57	0.56	0.86	0.93	0.63	0.42	0.57	0.11	0.01
Hispanic									
r	-0.10	-0.08	-0.14	-0.07	0.04	-0.23*	-0.10	-0.11	-0.13
P	0.30	0.45	0.22	0.54	0.74	0.04	0.39	0.37	0.28
Other European									
r	0.08	0.09	0.05	0.07	-0.19	-0.18	-0.14	-0.14	-0.16
P	0.40	0.41	0.63	0.54	0.09	0.13	0.24	0.23	0.20
Caucasian									
r	-0.04	0.12	0.03	-0.01	-0.05	0.04	0.05	-0.07	-0.19
P	0.67	0.27	0.82	0.95	0.67	0.70	0.64	0.56	0.12
Other									
r	0.06	-0.18	0.05	0.07	0.07	0.07	-0.14	-0.14	-0.16
P	0.55	0.09	0.63	0.54	0.55	0.52	0.24	0.23	0.20

r Pearson's Correlation Coefficient
P P-value

Table 14: Race and Ethnicity Correlated to Overweight BMI Percentile Over Time in All Subjects

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	0.05	-0.05	-0.07	0.18	-0.02	-0.10	0.01	-0.07	-0.35*
P	0.58	0.63	0.53	0.13	0.83	0.37	0.97	0.53	0.00
Hispanic									
r	0.00	0.04	0.12	0.08	-0.07	.035*	-0.15	0.02	0.19
P	0.98	0.72	0.29	0.49	0.55	0.02	0.21	0.85	0.13
Other European									
r	-0.06	-0.06	-0.03	-0.04	0.44*	0.24*	-0.06	-0.05	-0.05
P	0.56	0.56	0.78	0.73	0.00	0.03	0.58	0.66	0.67
Caucasian									
r	-0.03	0.00	0.03	-0.22	-0.04	-0.11	0.04	0.01	0.21
P	0.76	0.98	0.82	0.06	0.74	0.33	0.73	0.93	0.08
Other									
r	-0.04	0.26*	-0.03	-0.04	-0.03	-0.05	0.21	0.27*	0.28*
P	0.68	0.01	0.78	0.73	0.79	0.64	0.07	0.03	0.02

r Pearson's Correlation Coefficient
P P-value

Table 15: Race and Ethnicity Correlated to Obese BMI Percentile Over Time in All Subjects

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	-0.05	0.10	-0.12	-0.24*	-0.05	-0.04	-0.18	-0.14	-0.02
P	0.60	0.35	0.30	0.04	0.68	0.75	0.12	0.24	0.90
Hispanic									
r	0.26*	-0.06	0.15	0.14	0.10	-0.08	0.34*	0.13	0.00
P	0.01	0.58	0.20	0.22	0.39	0.49	0.00	0.29	1.00
Other European									
r	-0.03	-0.04	-0.03	-0.03	-0.04	-0.04	0.28*	0.23	0.24*
P	0.73	0.73	0.80	0.79	0.75	0.74	0.01	0.05	0.05
Caucasian									
r	-0.07	-0.06	0.06	0.19	0.02	0.10	-0.06	0.03	-0.03
P	0.46	0.59	0.59	0.10	0.89	0.38	0.60	0.78	0.78
Other									
r	-0.02	-0.03	-0.03	-0.03	-0.04	-0.04	-0.05	-0.06	-0.06
P	0.80	0.81	0.80	0.79	0.75	0.74	0.69	0.61	0.62

r Pearson's Correlation Coefficient
P P-value

Fruit and vegetable intake related to race and ethnicity in all subjects is shown in Tables 16-19. African American race was negatively correlated to fruit intake excluding juice at 12 months and 2 years of age (p=0.04, 0.00), as well as total fruit intake at 2 years of age (p=0.00), total vegetables and vegetables excluding French fries at 2.5 (p=0.01, 0.05) and 5 years of age (p=0.04, 0.04). African American race was positively correlated to total vegetable intake and vegetable intake excluding French fries at 3.5 years of age (p=0.03, 0.03).

Hispanic ethnicity was positively correlated to total fruit intake at 12 months of age (p=0.00), fruit intake excluding juice at 5 years of age (p=0.01), and vegetable intake excluding French fries at 2 years of age (p=0.01). Caucasian race was positively correlated to fruit intake excluding juice and total fruit intake at 2 years of age (p=0.00, 0.03), as well as total vegetable intake and vegetable intake excluding French fries at 2.5 years (p=0.00, 0.00) and 5 years of age (p=0.00, 0.00). Other European and other unspecified race or ethnicity were not significantly correlated to fruit and vegetable intake

Table 16: Race and Ethnicity Correlated to Total Fruit Intake Over Time in All Subjects

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	-0.08	0.06	-0.4	0.11	-0.09	0.1	0.03	-0.03	0.14
P	0.41	0.61	0.00**	0.35	0.45	0.42	0.81	0.82	0.28
Hispanic									
r	0.36	0.04	0.22	-0.19	-0.14	-0.03	-0.07	-0.12	0.11
P	0.00**	0.74	0.08	0.12	0.27	0.78	0.59	0.34	0.41
Other European									
r	-0.02	-0.2	-[1]	-0.13	0	-0.19	-0.14	-0.11	-0.14
P	0.82	0.09	0	0.29	0.99	0.11	0.22	0.36	0.26
Caucasian									
r	-0.05	-0.04	0.26*	0.03	0.21	-0.02	0.09	0.1	-0.12
P	0.6	0.71	0.03	0.82	0.09	0.89	0.45	0.43	0.36
Other									
r	-0.09	-[1]	0.12	-0.13	-0.11	-0.13	-0.1	0.07	-0.1
P	0.39	0	0.32	0.29	0.38	0.27	0.39	0.59	0.43

[1] Unobtainable as intake value was constant for this group
r Pearson's Correlation Coefficient
P P-value

Table 17: Race and Ethnicity Correlated to Fruit Intake Excluding Juice Over Time

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	-0.21	-0.13	-0.38	0.09	0.03	0.19	-0.15	0.11	-0.15
P	0.04*	0.29	0.00**	0.45	0.79	0.12	0.2	0.38	0.24
Hispanic									
r	0.13	0.05	-0.04	-0.09	-0.06	0.05	0.1	-0.01	0.34
P	0.21	0.68	0.77	0.47	0.64	0.69	0.39	0.91	0.01**
Other European									
r	0.12	-0.11	-[1]	-0.09	-0.01	-0.14	-0.12	-0.06	-0.1
P	0.23	0.35	0	0.47	0.94	0.23	0.3	0.64	0.44
Caucasian									
r	0.13	0.15	0.41	-0.02	0.03	-0.15	0.16	-0.08	0.04
P	0.21	0.21	0.00**	0.9	0.83	0.2	0.17	0.54	0.75
Other									
r	-0.05	-[1]	0.08	-0.09	-0.1	-0.1	-0.09	-0.06	-0.07
P	0.62	0	0.52	0.47	0.43	0.4	0.47	0.64	0.59

[1] Unobtainable as intake value was constant for this group
r Pearson's Correlation Coefficient
P P-value

Table 18: Race and Ethnicity Correlated to Total Vegetable Intake Over Time in All Subjects

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	-0.08	0.12	-0.12	-0.29	-0.01	0.27	0.1	-0.03	-0.26
P	0.43	0.33	0.35	0.01*	0.03*	0.03*	0.39	0.83	0.04*
Hispanic									
r	0.12	-0.14	0.22	-0.09	-0.13	-0.06	0.02	-0.15	-0.07
P	0.25	0.25	0.08	0.47	0.27	0.6	0.89	0.23	0.57
Other European									
r	0.04	-0.17	-[1]	-0.07	0.07	-0.11	-0.01	0.08	-0.1
P	0.68	0.16	0	0.57	0.56	0.38	0.95	0.52	0.43
Caucasian									
r	0	0	-0.02	0.37	0.08	-0.18	-0.11	0.08	0.4
P	0.97	0.97	0.85	0.00**	0.52	0.13	0.37	0.5	0.00**
Other									
r	0.03	-[1]	0.07	-0.02	-0.06	-0.08	-0.04	0.03	-0.12
P	0.74	0	0.56	0.85	0.64	0.52	0.74	0.79	0.37

[1] Unobtainable as intake value was constant for this group
r Pearson's Correlation Coefficient
P P-value

Table 19: Race and Ethnicity Correlated to Vegetable Intake Excluding French Fries Over Time in All Subjects

	12 months	18 months	2 years	2.5 years	3 years	3.5 years	4 years	4.5 years	5 years
African American									
r	-0.1	0.06	-0.11	-0.24	-0.08	0.25	-0.02	-0.03	-0.26
P	0.34	0.6	0.39	0.05*	0.49	.03*	0.85	0.82	0.04*
Hispanic									
r	0.16	-0.11	0.31	-0.06	-0.06	-0.06	0.04	-0.11	-0.14
P	0.12	0.33	0.01*	0.61	0.63	0.63	0.75	0.37	0.26
Other European									
r	0.05	-0.13	-[1]	-0.11	0.13	-0.08	-0.07	0.1	-0.08
P	0.65	0.29	0	0.35	0.28	0.51	0.55	0.45	0.52
Caucasian									
r	0.01	0.03	-0.07	0.33	0.11	-0.19	0.06	0.06	0.4
P	0.92	0.82	0.56	0.00**	0.37	0.11	0.63	0.66	0.00**
Other									
r	-0.01	-[1]	0.03	-0.11	-0.12	-0.06	-0.13	0.05	-0.1
P	0.9	0	0.81	0.38	0.31	0.63	0.29	0.7	0.42

[1] Unobtainable as intake value was constant for this group
r Pearson's Correlation Coefficient

P P-value

Maternal Smoking Status

Maternal smoking status was negatively correlated to normal BMI percentile at 5 years of age (p=-0.26) and positively correlated to overweight BMI percentile at 5 years of age as seen in Table 20.

Table 20: Maternal Smoking Status Correlated to BMI Percentile at 5 Years of Age in All Subjects

Maternal Smoking Status		Healthy Weight	Overweight	Obese
Never Smoked	r	.14	-.16	-.07
	P	.24	.19	.54
Smoked, Not While Pregnant	r	.10	-.09	-.01
	P	.40	.47	.90
Smoked While Pregnant	r	-.26*	.27*	.10
	P	.03	.03	.43

r Pearson's Correlation Coefficient
P P-value

Additionally, maternal smoking during pregnancy was positively correlated with underweight BMI percentile at 2.5 years of age (p=0.026), 3 years of age (p=0.003), and 4 years of age (p=0.032). Smoking before pregnancy was negatively correlated with vegetable intake excluding juice at 18 months of age (p=0.04) and fruit intake excluding juice at 2 years of age (p=0.05).

Television Viewing

Television data was reported as hours of use in the home as well as hours viewed by the subject. As seen in Table 21 no significant correlations between television viewing from12 months to 2.5 years of age and BMI percentile at 5 years of age were found. However, television viewing did correlate with a number of BMI percentiles at other ages.

Reported hours of home television use at 12 months of age was positively correlated to overweight BMI percentile at 12 months of age (p=0.017) and obese

BMI percentile at 3.5 years of age (p=0.026) as well as negatively associated with underweight BMI percentile at 3 years of age (p=0.018) and 4 years of age (p=0.040). Hours of home television use at 2 years of age were positively associated with obese BMI percentile at 3 years of age (p=0.001) and 3.5 years of age (p=0.024). No associations were found between hours of home television use at 18 months or 2.5 years of age and BMI percentile.

Hours of television viewed by the child at 18 months and 2.5 years of age were associated with BMI percentile. Hours of television viewed by the child at 18 months of age were positively correlated to underweight BMI percentile at 2 years of age (p=0.028), 3 years of age (p=0.006) and 4 years of age (p=0.020). Hours of television watched by the child at 2.5 years of age were positively correlated to overweight BMI percentile at 2.5 years of age (p=0.032) and obese BMI percentile at 18 months of age (p=0.039) as well as negatively correlated with underweight BMI percentile at 3 years of age (p=0.043). Television viewed at 12 months and 2 years of age were not significantly correlated to BMI percentile.

Table 21: Television Viewing Correlated to BMI Percentile at 5 Years of Age in All Subjects

TV Viewing	Age		Healthy Weight	Overweight	Obese
TV On Time	12 months	r	-.15	.12	.07
		P	.22	.32	.55
Child TV Watch		r	-.03	.09	-.02
		P	.82	.49	.85
TV On Time	18 months	r	-.07	.04	.08
		P	.58	.76	.55
Child TV Watch		r	-.20	.21	.08
		P	.11	.10	.52
TV On Time	2 years	r	-.13	-.07	.15
		P	.31	.56	.22
Child TV Watch		r	.03	-.03	.00
		P	.79	.82	1.00
TV On Time	2.5 years	r	-.03	.02	.02
		P	.84	.88	.85
Child TV Watch		r	-.13	.05	.11
		P	.31	.67	.38

r Pearson's Correlation Coefficient
P P-value

Reported hours of home television use at the subject's 12-month clinic visit was positively correlated to total vegetable intake at 12 months of age (p=0.03). Reported hours of home television use at 2 years of age was negatively correlated to total fruit intake at two years of age (p=0.04).

Hours of television viewed by the child at 12 months of age was negatively correlated to total vegetable intake at 4.5 years of age (p=0.04). Hours of television viewed by the child at 2 years of age was positively correlated to total vegetable intake and vegetable intake excluding French fries at 12 months of age (p=0.02, 0.03) as well as total fruit intake at 4.5 years of age (p=0.03).

Hours of television viewed by the child at 2.5 years of age was positively total fruit intake at 18 months (p=0.02), and 2 years of age (p=0.05) as well as negatively correlated to vegetable intake excluding French fries at 4 years of age (p=0.03).

Total Daily Energy Intake

Table 22 shows the mean total energy intake over time by BMI group. As seen in Figure 8 caloric intakes of BMI groups at 12 months and 5 years of age are very similar. Energy intake in those with overweight and obese BMI percentiles at 5 years of age fluctuates more between 12 months and 5 years of age compared to energy intake in those with healthy weight BMI.

Table 22: Total Daily Energy Intake Over Time by BMI Category at 5 Years of Age

BMI Group	Age	Mean ± SD	Minimum	Maximum
Healthy Weight	12 months	1095 ± 328	444	1860
Overweight		1210 ± 350	816	1651
Obese		1228 ± 393	654	1858
Healthy Weight	18 months	1289 ± 358	562	1994
Overweight		1383 ± 458	838	2040
Obese		1293 ± 507	501	2150
Healthy Weight	2 years	1387 ± 424	636	2169
Overweight		1674 ± 350	1257	2416
Obese		1464 ± 537	778	2281
Healthy Weight	2.5 years	1436 ± 388	726	2436
Overweight		1546 ± 334	978	2045
Obese		1570 ± 237	1163	1904
Healthy Weight	3 years	1484 ± 377	792	2360
Overweight		1518 ± 456	894	2558
Obese		1756 ± 341	1042	2220
Healthy Weight	3.5 years	1502 ± 532	622	2927
Overweight		1493 ± 387	938	2071
Obese		1964 ± 474	1446	3057
Healthy Weight	4 years	1646 ± 573	669	3239
Overweight		1630 ± 293	933	2035
Obese		1576 ± 468	984	2710
Healthy Weight	4.5 years	1678 ± 545	897	2981
Overweight		1688 ± 179	1376	1956
Obese		1789 ± 671	1056	2882
Healthy Weight	5 years	1895 ± 628	823	3179
Overweight		1650 ± 223	1311	2029
Obese		1699 ± 472	1020	2676

Figure 8: Mean Daily Energy Intake Over Time by BMI Category at 5 Years of Age

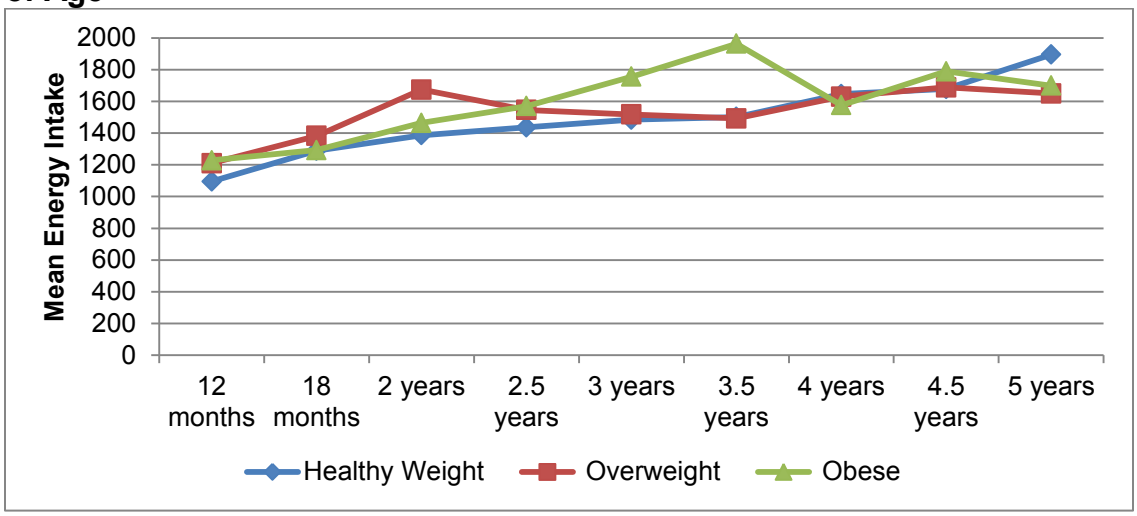


Table 22 shows mean daily energy intake over time correlated to BMI category at 5 years of age. Only two significant correlations were found. Obese BMI percentile was positively correlated to total daily energy intake at 3 and 3.5 years of age.

Table 23: Energy Intake Correlated to BMI Percentile at 5 Years of Age

Age		Healthy Weight	Overweight	Obese
12 months	r	-0.18	0.08	0.13
	P	0.16	0.51	0.29
18 months	r	-0.05	0.08	-0.02
	P	0.68	0.55	0.91
2 years	r	-0.21	0.24	0.01
	P	0.12	0.07	0.94
2.5 years	r	-0.13	0.09	0.14
	P	0.31	0.49	0.30
3 years	r	-0.20	-0.03	0.29
	P	0.11	0.80	0.02*
3.5 years	r	-0.22	0.08	0.36
	P	0.08	0.53	0.00**
4 years	r	0.04	0.00	-0.05
	P	0.76	0.99	0.71
4.5 years	r	-0.04	0.00	0.08
	P	0.77	0.97	0.52
5 years	r	0.19	-0.15	-0.10
	P	0.16	0.27	0.44

r Pearson's Correlation Coefficient
P P-value

CHAPTER V

Discussion

This study finds overweight and obesity rates rise as children get older, with the most dramatic change occurring at 3 years of age. Fruit and vegetable intake does not appear to be predictive of either healthy weight or overweight and obesity at 5 years of age, similar to previous studies (1, 2, 25). Maternal smoking during pregnancy was positively correlated to overweight at 5 years of age, and was negatively correlated to healthy weight at 5 years of age. This is consistent with a previous analysis of the same cohort (36) as well as current literature (41-44).

While no correlation was found between fruit and vegetable intake and BMI percentile at 5 years of age, some differences in intake were observed between BMI groups. The healthy weight group met or exceeded recommendations for fruit intake including juice at all but one age (5 years), whereas the overweight group did not meet fruit recommendations at five ages. The obese group also did not meet fruit recommendations at only one age (4.5 years). For vegetable intake including French fries the healthy weight group met recommendations at five ages, while the overweight group met recommendations at four ages and the obese group met recommendations at seven ages.

Energy intake over time also differed slightly between groups. At 12 months of age the healthy weight, overweight, and obese groups had very similar mean energy intakes, within 133 calories. And again at 5 years of age mean energy intake in the normal weight, overweight, and obese groups was similar, within

200 calories. However, when evaluating the trend of mean caloric intake over time among each group the healthy weight group has a steady upward trend while the overweight and obese groups have increases and decreases over the years.

Unlike other studies (45-48), income was not related to BMI percentile in this population. Income was however positively correlated with an increased fruit intake. This discrepancy could be attributed to the way income was measured in this study from subject's zip code. The correlation seen between higher income and higher fruit intake could signify a relationship between eating pattern and neighborhood rather than income. This is consistent with a previously reported association between community and nutrition intake in Michigan (45).

African American race was negatively correlated to overweight and obesity and positively correlated to normal weight in this population despite being negatively correlated with fruit and vegetable intake at a number of study time points. Conversely, Hispanic ethnicity was positively correlated to overweight and obesity as well as negatively correlated to normal weight while being positively correlated with fruit and vegetable intake. This puzzling dynamic is also present in national studies. NHANES data from 2009-2010 show slightly higher rates of overweight but not obesity in Hispanic children (33.1% overweight, 16.2% obese) compared to Non-Hispanic black children (28.9% overweight, 18.9% obese) (10). NHANES data from 1992-2002 showed Mexican American children in the United States consumed significantly more fruit (1.16) than did Non-Hispanic African American children (1.05 servings) (15).

This relationship between African American children who consume fewer fruits and vegetables and have lower rates of overweight and obesity than Hispanic children who consume more fruit but have higher rates of overweight and obesity is perplexing. It is likely that physical activity or genetic factors are in play, neither of which were controlled for in this study or in previous analyses.

This population had 15.7% overweight and 20.0% obesity at age five. Compared to national figures of 26.7% overweight and 12.1% obesity (10), this study population contains more obese and fewer overweight children. Potential reasons for this discrepancy with national data include a difference in racial and ethnic distribution of the samples. Ogden, et al. gleaned data from the NHANES 2009-2010 population which was 19.3% Non-Hispanic Black, 33.5% Non-Hispanic White, and 40.4% Hispanic, compared to this population which was 65.7% African American, 24.3% Caucasian, and 7.1% Hispanic.

According to previous studies 2 to 5 year olds consume on average 1.29 cups of fruit and 0.76 cups of vegetables per day. This study population consumed an average of 1.02 cups fruit and 0.93 cups of vegetables at 5 years of age. Of those averages 58% of fruit intake was comprised of juice and 17% of total vegetable intake was composed of French fries compared to 38% and 28% nationwide. This study population consumes more vegetables and more fruit juice compared to national statistics.

While fruit and vegetable intake was not shown in this analysis to affect BMI percentile, many possible mechanisms for an affect exist. One previously studied mechanism is energy density. In adults, evidence suggests those who eat the

recommended amounts of fruits and vegetables have lower body weights and lower energy dense diets compared to those who do not (49). Similarly, Vernarelli et al. found dietary energy density was positively associated with body weight in children aged 2 to 8 years while low-energy dense diets contained higher amounts of fruits and vegetables (28). Various intervention studies have shown replacing higher energy-dense foods with fruits and vegetables was associated with increased satiety and lower energy intake in adults (50). These studies were however, conducted in adults, making generalizability to children difficult, and often they were not specifically designed to test fruit and vegetable intake.

When originally proposed this study was to conduct a longitudinal analysis of fruit and vegetable intake with BMI following specific individuals. However, only seven participants had all 9 recalls available with none deemed unreliable by the research staff. This lack of subject volume required a change in plans for analysis at which time it was observed that no trend in fruit or vegetable intake occurred over the study period as anticipated. Generally, all the subjects were consuming very few fruit and vegetables at each age of assessment. This over-all low intake of fruits and vegetables could potentially account for the lack of relationship between fruit and vegetable intake and BMI percentile.

Limitations

An obvious limitation in this study is the absence of physical activity data, which is related to energy balance and shown to correlate with BMI in children (51). Television viewing time was collected to potentially control for sedentary

behavior, however data were only available through 2.5 years of age. Additionally, errors may exist in 24-hour recalls from older children as many of them had trouble remembering what they ate at school or day care.

Future studies

Due to the relationship identified in other research and here between income and diet pattern and incidence of overweight and obesity it is evident we need to find an intervention that is appropriate for lower income families.

Also important would be to find an intervention to combat maternal smoking during pregnancy, which was strongly associated to increased overweight and obesity in this analysis and elsewhere.

More longitudinal cohort studies evaluating childhood eating patterns and lifestyle behaviors are still needed to further illuminate the reason for increasing childhood overweight and obesity. Controlling for confounding variables is challenging when studying overweight and obesity. Future studies must better assess confounders like physical activity, calorie intake, screen time, parental income, and genetic factors.

Indications for Clinical Practice

Childhood overweight and obesity is a multi-factorial disease requiring interventions in many areas. There is no magic pill or single sure-fire way to change a child's overweight or obesity risk. All factors must be considered when evaluating overweight and obesity treatment including environmental exposures, diet, physical activity, family environment, socioeconomic status, and community.

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APPENDIX A

Parent Consent Form: Original Study Birth-18 months

CONSENT FORM

The Effects of Infant Formula Supplemented with Long Chain Polyunsaturated Fatty Acids on Visual Development in Term Infants

Protocol #3370-4
Sponsor: Mead Johnson, Inc.

INTRODUCTION

As a woman who has delivered a term infant and who has specified that I plan to feed formula to my infant, I am being invited to enroll my child in a research study of infant formula. My baby and I are being asked to enroll at Truman Medical Center or the University of Kansas Medical Center because the investigators need to know the level of the nutrient studied in my blood and my baby's cord blood after my baby is born. The remainder of the study will be conducted at the University of Kansas Medical Center by Susan Carlson, Ph.D. Approximately 185 subjects will be enrolled in this study.

I do not have to allow my child to participate in this research study. It is important that before I make a decision for my child to participate, I read the rest of this form. I should ask as many questions as I need to understand what will happen if my baby and I participate in the study.

BACKGROUND

Two fats, docosahexaenoic acid (DHA) and arachidonic acid (ARA), are found in very large amounts in the brain. DHA and ARA are important for infant brain development and behavior, including how my baby sees and learning. My baby obtained DHA and ARA from me during the last three months of my pregnancy. Breast feeding is the preferred way to feed in terms of the best interests of the baby. Breast milk also contains DHA and ARA. Breast milk and formulas also contain fats that most babies can change to DHA and ARA.

Infants born early have been shown to have higher development when they consume formulas with DHA or DHA and ARA. This means that preterm infants do not make as much DHA and ARA as they need for best development from the nutrients in infant formula. Term babies (such as my baby) may or may not need DHA and ARA. Some studies indicate they do and others indicate they do not. Some formulas in the US contain DHA and ARA and some do not.

PURPOSE

The purpose of this study is to determine if term infants have higher development when they drink formulas with DHA and ARA. Another purpose is to determine if the amount of DHA and ARA in the formula is important. Human milk DHA can be as low as 0.05% and as high as 2.8%, depending upon a woman's diet. This study will test a range of formula DHA from 0.32% to 0.96% against a formula without DHA or ARA (marketed Enfamil). Infants will be tested for vision, attention (how babies look at faces, look and play with toys), learning, motor and language development.

PROCEDURES

If I choose to enroll my infant in this study after hearing about how the study will be conducted, and what I and my child will need to do, the investigators will record some

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information from my medical record and my delivery including the weight I gained during pregnancy, my smoking history, and my baby's weight, length and head circumference. The investigators will also try to get cord blood for analysis of nutrients in my baby's blood and a sample of my blood when it is drawn after I deliver as part of routine blood work related to my pregnancy. The same nutrients will be analyzed in my blood at the University of Kansas Medical Center.

I will be sent home with an appointment to bring my baby to the University of Kansas Medical Center in about 1 week and given enough marketed Enfamil to feed him/her until that visit (visit 1).

Visit 1 (7-9 days of age) My baby will be weighed and measured. I will be asked what my baby has eaten in the past 24 hours. If I still plan to feed him/her formula, he/she will be assigned by chance (like pulling numbered pieces of paper out of a hat) to one of the following 4 formulas:

- Milk based infant formula containing 0.32% of the total fatty acids as DHA and 0.64% of the total fatty acids as ARA (same as marketed Enfamil Lipil)
- Milk based infant formula containing 0.64% of the total fatty acids as DHA and 0.64%of the total fatty acids as ARA
- Milk based infant formula containing 0.96% of the total fatty acids as DHA and 0.64% of the total fatty acids as ARA
- Milk based Infant Formula without DHA or ARA (same as marketed Enfamil)

I will receive 7 cases of ready-to-feed study formula at this visit. The visit should last about 30 minutes.

Visit 2 (6 weeks of age): The investigators will measure how my baby sees using a test that involves placing 3 electrodes directly on my baby's head. The process involves cleaning the area then placing a small amount of paste similar to toothpaste on the head. The electrodes are placed on top of the paste. The electrodes will be used to record my baby's brain waves while he/she is looking at pictures. My child's weight, height and head circumference will be measured again and I will be asked questions about what my baby eats. I will also be asked questions about my baby's bowel movements including color, number and consistency. I will be asked to report if my baby has been fussy, gassy or had constipation or diarrhea. I should let the investigator know if my baby has been sick or not acting well since his/her last visit. I will receive 13 cases of ready-to-feed study formula at this visit. The visit should last about 40 minutes.

Visit 3 (4 months of age): The investigators will measure how my baby sees using the same test as before and another test. My baby will wear a pair of plastic glasses during the second test. My baby's height, weight and head circumference will be measured. In another test, my child will be given an object to look at several times. The investigator will measure how long he/she looks at the object and how quickly he/she stops looking at the object. My baby's heart rate will be measured during the test.

My baby will have a blood sample collected by either heel stick or drawn from a vein. The investigator may use a cream or spray that will numb the area before obtaining the sample. One-half teaspoon of blood will be drawn.

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I will be asked questions about how much formula my baby drank over the past 24 hours. I will also be asked questions about my baby's bowel movements including color, number and consistency. I will be asked to report if my baby has been fussy, gassy or had constipation or diarrhea. I should let the investigator know if my baby has been sick or not acting well since his/her last visit. I will receive 10 cases of ready-to-feed study formula at this visit. The visit will take 60-90 minutes.

Visit 4 (6 months of age): The investigators will measure how my baby sees using the test that requires him/her to where a pair of plastic glasses. In another test, he/she will be given an object to look at several times (just like at 4 months of age). The investigator will measure how long he/she looks at the object and how quickly he/she stops looking at the object. My baby's heart rate will be measured during the test. My baby's height, weight and head circumference will be measured. I will be asked questions about what my baby eats. I will also be asked questions about my baby's bowel movements including color, number and consistency. I will be asked to report if my baby has been fussy, gassy or had constipation or diarrhea. I should let the investigator know if my baby has been sick or not acting well since his/her last visit. I will receive 16 cases of ready-to-feed study formula at this visit. The visit should take 40 -60 minutes.

Visit 5 (9 months of age): My baby will have both tests that measure how he/she sees. In another test, my child will be given an object to look at several times (just like at 4 and 6 months of age). The investigator will measure how long he/she looks at the object and how quickly he/she stops looking at the object and my baby's heart rate will be measured during the test. My baby's height, weight and head circumference will be measured. I will be asked questions about what my baby eats. I will also be asked questions about my baby's bowel movements including color, number and consistency. I will be asked to report if my baby has been fussy, gassy or had constipation or diarrhea. I should let the investigator know if my baby has been sick or not acting well since his/her last visit. I will receive 4 cases of ready to-feed study formula at this visit. The visit should take about 40-60 minutes

Visit 6 (10 months of age): During this visit the baby will be placed on the parent or guardian's lap in front of a small table. A test will be completed with a small toy, foam block and 2 clothes that will be placed in front of the child. The investigator will describe this test to me in detail before it has been completed. I will also take a short language test. The small toy will be given to my child to keep. I should let the investigator know if my baby has been sick or not acting well since his/her last visit. I will be asked questions about what my baby eats. I will receive 10 cases of ready-to-feed study formula at this visit. I will be asked to bring any unopened cases of study formula to the next visit. The visit should take about 30 minutes.

Visit 7 (12 months of age): I will bring any unopened cases of study formula to this visit. I can feed any cans of formula that remain in an opened case before changing my baby's milk to whole cows' milk. The investigators will measure how my baby sees using both vision tests. My child will be video-recorded while playing with an interesting toy and the investigator will use the recording to measure some aspects of attention. My child will have a blood sample collected by either heel stick or drawn from a vein. The investigator may use a

cream or spray that will numb the area before obtaining the sample. Approximately ½ teaspoon of blood will be drawn. My child's height, weight and head circumference will be measured. I will be asked questions about what my baby eats. I will also be asked questions about my child's bowel movements including color, number and consistency. I will be asked to report if my child has been fussy, gassy or had constipation or diarrhea. I should let the investigator know if my child has been sick or not acting well since his/her last visit. The visit should take about 2 hours.

Visit 8 (18 months of age): The investigators will measure how my baby sees using the test that he/she had while wearing plastic glasses. My child will be video-recorded while playing with an interesting toy and the investigator will use the recording to measure some aspects of attention. My child will also be given a standardized test to measure mental and physical development. My child's height, weight and head circumference will be measured. I will be asked questions about what my baby eats. I will be asked questions about my child's language skills. I should let the investigator know if my child has been sick or not acting well since his/her last visit. The visit should take about 2 hours. It is important that my child be rested before the testing at this visit. If for some reason, he/she is not capable of completing all of the assessment, I may be offered the possibility to bring him/her on another day.

RISKS

It is possible that my child could be at risk by participating in this study. Risks of the study formulas may include: not being able to tolerate the formula, spitting up, vomiting, constipation, diarrhea, red itchy skin, rashes or other signs of food allergy and failure to thrive or temporary impairment of growth.

Enfamil Lipil, one of the formulas in this study has been available in stores for the past year. During that year, parent reports of formula problems have been recorded by Mead Johnson Nutritionals, the sponsor of this study. There have not been more problems with Enfamil Lipil than with Enfamil, another formula that will be fed in this study. Two of the formulas have higher DHA and ARA than Enfamil Lipil. None of the formulas fed in this study has more DHA and ARA than has been measured in some human milk, however, higher intakes of DHA and ARA may have some risks that have not yet been identified or unexpected side effects that have not been previously observed.

The importance of DHA and ARA for infants is controversial. Some experts think babies should consume formula with DHA and ARA, others do not. The American Academy of Pediatrics and the FDA have not given the opinion that formulas need to contain DHA and ARA. However, it is possible that my baby might benefit from DHA and ARA and not receive DHA and ARA if he/she is assigned to the formula without DHA and ARA.

Some redness, soreness, or bruising may occur at the site of blood sampling. There is also a very slight risk of infection.

NEW FINDINGS STATEMENT

Any problems of babies in the study will be recorded. I will be informed if any significant new findings develop during the course of the study that may affect my willingness to allow my child to participate in this study.

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BENEFITS

My child may or may not benefit from participating in this study. It is hoped that additional information gained in this research study may be useful in the growth and development of infants. I will receive a video recording of my infant doing the 4, 6 and 8 month looking test when the 8 month visit is complete.

ALTERNATIVES

Formulas with no DHA and ARA and formulas with the lower level of DHA and ARA in this study are available in stores and from WIC (Women Infant Children Supplemental Feeding Program). Name brand formulas that contain DHA and ARA are Enfamil Lipil and Similac Advance. Name brands that do not contain DHA and ARA are Enfamil and Similac. As noted above, two of the formulas fed in this study are the same as Enfamil and Enfamil Lipil. The other formulas contain 2 and 3 times as much DHA as Enfamil Lipil and the same amount of ARA. Store brands of formula are also available locally (for example, Costco, Walmart) without DHA and ARA.

COSTS

Infant formula will be provided to me at no cost while my child is participating in this study. The investigators will work with WIC at Truman Medical Center to make sure that I receive baby foods other than formula until my baby is 12 months old. I will not incur any costs because of my child's participation.

PAYMENT TO SUBJECTS

I will receive a check for $50 at each visit to the University of Kansas Medical Center to cover the costs of transportation and to partially compensate me for my time required to participate in the study. There will be 8 regularly scheduled visits in 18 months. If an additional visit is required because my infant is unable to complete all of the testing at 18 months, I will receive an additional payment of $50 for another visit.

My name, address, social security number, and the title of this study will be given to the KUMC Research Institute. This is done so that the Research Institute can write a check for study payments. Payments are taxable income.

DISCLOSURE OF FINANCIAL INTERESTS

The principal investigator has been paid as a consultant and for program presentation on DHA for Mead Johnson Nutritionals (the sponsor). The University of Kansas Medical Center Conflict of Interests Committee monitors this research project to make it less likely that these financial interests inappropriately influence how the study is conducted. However, you should make your own decision about whether these financial interests affect your decision to participate. If you have any questions about this financial relationship, you may discuss them with the investigator or with the Research Compliance division at 913-588-5492.

IN THE EVENT OF INJURY

In the event my child experiences any serious health problem (hospitalization, life-threatening illness or death) for any reason while participating in this study, I should immediately seek treatment or help in the way I normally would as if my child were not in a study. I should let

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Susan Carlson, Ph.D. know about any of these problems as soon as possible by calling her office (913-588-5359) between 8:30 and 5:30 Monday through Friday. If it is after 5:30 PM on a weekday, or it is a holiday or weekend, I should call Dr. Carlson at home (816 -960-1805). A message may be left at both numbers in the event that Dr. Carlson is not immediately available.

INSTITUTIONAL DISCLAIMER STATEMENT

Although the University of Kansas Medical Center does not provide free medical treatment or other forms of compensation to persons injured as a result of participating in research, such compensation may be provided under the terms of the Kansas Tort Claims Act. If I believe my child has been injured as a result of participating in research, I should contact the Office of Legal Counsel, University of Kansas Medical Center, Kansas City, KS 66160-7101. I do not give up any of my or my child's rights by signing this form.

It is not the policy of the University of Missouri nor Truman Medical Center to compensate human subjects in the even the research results in injury. The University of Missouri and Truman Medical Center, in fulfilling their public responsibilities, have individually and separately provided liability coverage for any physical injury in the event such injury is caused by the negligence of the University of Missouri, its faculty or staff or Truman Medical Center and its employees. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries as a result of participating in the research projects of the University of Missouri. In the event I believe that I have suffered any physical injury as the result of my participation in the research program, I may contact Dr. Susan Carlson, 913-588-5359, or Sheila Anderman, Research Administrator of the University of Missouri-Kansas City Adult Health Sciences Institutional Review Board, telephone number 816-235-6150, who can review the matter with me and provide further information on how to proceed.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

Names of subjects or information identifying subjects will not be released without written permission unless required by law. Study data will be recorded on the sponsor's forms and sent to the sponsor or their designee. Videotapes of my baby when he/she is looking at pictures and playing with toys will be used only by the investigators and their students and to make a videotape copy for me. The videotapes will be secured under lock and key like all of other information that could be linked directly to my child. The videotape of my child will not be shown without specific permission from me and even then would not identify my child by name. Efforts will be made to keep my and my child's personal information confidential. Researchers cannot guarantee absolute confidentiality. If the results of this study are published or presented in public, information that identifies my baby will be removed.

The privacy of my and my child's health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). If I choose to allow my child to participate in this study, I will be asked to give permission for researchers to use and disclose my and my baby's health information that is relevant to the study.

To perform this study, researchers will collect health information about me and my child from his/her medical record and from the study activities that are listed in the Procedures section of this consent form. My and my baby's study-related health information will be used at KU

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Medical Center by Dr. Carlson, members of the research team, Truman Medical Center, the KU Hospital Medical Record Department, the KUMC Research Institute and officials at KUMC and at Truman Medical Center that oversee research, including the KUMC Human Subjects Committee, the IRB that governs Truman Medical Center and other committees and offices that review and monitor research studies.

Dr. Carlson and her team may share information about me and my baby with representatives of Mead Johnson (the sponsor of the study), the monitoring company who verifies study data, the laboratory that processes study lab samples, other business partners of the sponsor who help with the study, Mead Johnson's Data Coordinating Center, Mead Johnson's designated Data and Safety Monitoring committee, the U.S. Food and Drug Administration (FDA), and U.S. agencies that govern human research (if and when regulatory compliance issues arise). My and my child's information will be shared in order to analyze and confirm the results of the study.
Some of the persons or groups that receive my and my baby's study information may not be required to comply with HIPAA privacy laws. My and my child's information may lose its federal protection if those persons or groups disclose it.

Permission granted on this date to use and disclose my health information remains in effect indefinitely. By signing this form I give permission for the use and disclosure of my and my child's information for purposes of the study at any time in the future.

Any research information that is placed in my and my child's medical record will be kept indefinitely.

QUESTIONS

I have read the information in this form. Dr. Carlson or her associates have answered my question(s) to my satisfaction. I know if I have any more questions after signing this I may contact Dr. Carlson or one of her associates at (913) 588-5359. If I have any questions about my child's rights as a research subject, I may call (913) 588-1240 or write the Human Subjects Committee, University of Kansas Medical Center, 3901 Rainbow Blvd. MSN 1032, Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

My and my child's participation in this study is voluntary and that the choice not to participate or to quit at any time can be made without penalty or loss of benefits. Not participating or quitting will have no effect upon the medical care of treatment my child receives now or in the future at the University of Kansas Medical center. The entire study may be discontinued for any reason without my consent by the investigator conducting the study, by the sponsor of the study, or the FDA. My child's participation can be discontinued by the investigator or by the sponsor if it is felt to be in my child's best interest or if I do not follow the study requirements. If I choose to withdraw before my child is 18 months of age, I may be asked to answer questions about the study on the telephone.

If I want to cancel permission to use my or my child's health information, I should send a written request to Dr. Carlson. The mailing address is Susan Carlson, Ph.D., Dept. of Dietetics and Nutrition, 4019 Delp, University of Kansas Medical Center, 3901 Rainbow

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Boulevard, Kansas City, KS 66160. If I cancel permission to use my child's health information, the research team will stop collecting any additional information about my child, unless they need information about a side effect of the milk-based formula. The information that was collected before my cancellation, and any information about side effects, will be sent to the study sponsor.

Should the study be terminated prior to the completion of my and my child's participation, neither the sponsor, the investigator, nor the University of Kansas Medical Center will be under any obligation to provide me with the milk-based formula used in the study. My child's physician will decide upon further treatment after study termination, if indicated.

CONSENT

Dr. Carlson or her associates have given me information about this research study. They have explained what will be done and how long it will take. They explained the inconvenience, discomfort and risks that may be experienced during this study.

By signing this form, I give my permission for my and my child's health information to be used and disclosed for the purposes of this research study. If I choose not to sign this form, my child and I will not be able to participate in the study.

I voluntarily consent to allow my child and I to participate in this research study. I have read the information in this form and have had an opportunity to ask questions and have them answered. ***I will be given a copy of the signed form to keep for my records.***

_____
Type/Print Subject's Name

_____ _____ _____
Signature of Subject Time Date

_____
Type/Print Name of Witness

_____ _____
Signature of Witness Date

_____
Type/Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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APPENDIX B

Parent Consent Form: Follow-up Study 2-6 Years

CONSENT FORM

The Effects of Infant Formula Supplemented with Long Chain Polyunsaturated Fatty Acids on Cognitive Development in Children

Protocol #10205
Sponsor: Mead Johnson, Inc.

INTRODUCTION

As a parent who enrolled my child in a study of infant formula between birth and 18 months, I am being asked if I will permit my child to be studied with more tests of infant development at 7 more ages (9 more times) ending when he/she reaches 6 years of age. The study will be conducted at the University of Kansas Medical Center by Susan Carlson, Ph.D. and other members of her study team. Up to 110 children will be studied.

I do not have to allow my child to participate in this research study. It is important that before I make a decision for my child to participate, I read the rest of this form. I should ask as many questions as I need to understand what will happen if my baby and I participate in the study.

BACKGROUND

Two fats, docosahexaenoic acid (DHA) and arachidonic acid (ARA), are found in very large amounts in the brain. DHA and ARA are important for infant brain development and behavior, including how my baby sees and learning. My baby was enrolled in a study that provided varying amounts of DHA and ARA when he/she was an infant. Until 18 months, my infant/toddler was followed for his/her development. Now the investigator (Dr. Carlson) has been given additional money to follow children from that study until they are 6 years of age.

PURPOSE

The purpose of the original study was to determine if term infants have higher development when they drink formulas with DHA and ARA. Another purpose was to determine if the amount of DHA and ARA in the formula is important. My baby had tests of, vision, attention (how babies look at faces, look and play with toys), learning, motor and language development. These are still the purposes of the study. This new consent would permit the investigators to continue studying my child's development until he/she was near school age. Child development experts believe that any benefits of formulas with DHA and ARA would become bigger as children became older.

PROCEDURES

If I choose to enroll my infant in this study after hearing about how the study will be conducted, and what I and my child will need to do, I will be given an appointment to bring my child in when he or she is 2 years old. At the 2-year appointment and all subsequent appointments, it is important that my child not be tired or sick so that he/she can do his/her best. The investigators will work with me to find a time of day that is a good one for his/her appointment.

Visit 1 (2 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. I will be asked to complete a questionnaire about my child's experiences and environment. During

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this visit the child will sit in a toddler chair in front of a small table. A test will be completed with a small toy, in which the toy is hidden in one of two places in front of the child. My child will also be shown how to put together small toys and will be given a chance to do so. In addition, my child will play with interesting toys. The investigator will describe these tests to me in detail before each is started. This visit will be videotaped and I will be with my child the whole time. I will also complete a survey about my child's everyday behavior. This visit will take approximately 1.5 to 2 hours.

Visit 2 (2.5 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. During this visit the child will sit in a chair in front of a small table. A test will be completed with a small toy, in which the toy is hidden in one of two places in front of the child. My child will also be shown how to put together small toys and will be given a chance to do so. In addition, my child will play with interesting toys. The investigator will describe these tests to me in detail before each is started. This visit will be videotaped and I will be with my child the whole time. This visit will take approximately 1.5 hours.

Visit 3 (3 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. During this visit the child will sit in a chair in front of a small table. A test will be completed with a small toy, in which the toy is hidden in one of two places in front of the child. In addition, my child will be shown cards and asked for a response to them or asked to sort them into piles. The investigator will describe these tests to me in detail before each is started. This visit will be videotaped and I will be with my child the whole time. This visit will take approximately 1.5 hours.

Visit 4 (3.5 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. During this visit the child will sit in a chair in front of a small table. A test will be completed with a small toy, in which the toy is hidden in one of two places in front of the child. In addition, my child will be shown cards and asked for a response to them or asked to sort them into piles... The investigator will describe these tests to me in detail before each is started. The visit will be videotaped and I will be with my child the whole time. This visit will take approximately 1.5 hours.

Visit 5 (4 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. In addition, my child's blood pressure will be taken. During this visit the child will sit in a chair in front of a small table. My child will be given a set of cards and asked to sort them into piles and will play a game in which monkeys will be placed in a tree according to a few rules. My child will be given a set of cards and asked to sort them into piles or give a certain response to a card. In addition, my child will be shown and set of pictures in a certain order and will be given a chance to put those pictures in order. The investigator will describe these tests to me in detail before each is started. The visit will be videotaped and I will be with my child the whole time. This visit will take approximately 1.5 hours.

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Visit 6 (4.5 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. I will be asked to complete a questionnaire about my child's experiences and environment. My child's blood pressure will be taken. During this visit, 24 sensors will be placed on my child's head and 2 additional sensors will be placed on my child's chest. This procedure involves using a cotton swab to gently clean the area where each sensor will be placed and then sticking the sensor in place using a paste that washes out with water. After the sensors are in place, my child will be shown how to play a computer game in which buttons are pressed when certain pictures come up on a television screen or will be asked simply to watch pictures on the television. My child's brain activity and heart rate will be recorded during the computer games. The investigator will describe these tests to me in detail before each is started. I will be with my child the whole time. You will be asked some questions about your child's health and home life. This visit will take approximately 1.5 hours.

Visit 7 (5 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. In addition, my child's blood pressure will be taken. During this visit the child will sit in a chair in front of a small table. My child will be given a set of cards and asked to give a certain response to a card and will play a game in which monkeys will be placed in a tree according to a few rules. In addition, my child will be shown and set of pictures in a certain order and will be given a chance to put those pictures in order. The investigator will describe these tests to me in detail before each is started. The visit will be videotaped and I will be with my child the whole time. In addition, my child will be given a test of language abilities. You will be asked some questions about events in your child's life and his or her behavior. This visit will take approximately 1.5 hours.

Visit 8 (5.5 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. My child's blood pressure will be taken. During this visit, 34 electrical sensors will be placed on my child's head and 2 additional sensors will be place on my child's chest. This procedure involves using a cotton swab to gently clean the area where each sensor will be placed and then sticking the sensor in place using a paste that washes out with water. After the sensors are in place, my child will be shown how to play a computer game in which buttons are pressed when certain pictures come up on a television screen or will be asked simply to watch pictures on the television. My child's brain activity **and heart rate** will be recorded during the computer games. The investigator will describe these tests to me in detail before each is started. I will be with my child the whole time. You will be asked some questions about your child's health and home life. This visit will take approximately 1.5 hours.

Visit 9 (6 years of age): My child will be weighed and measured. I will be asked what my child has eaten in the past 24 hours and questions about my child's general health. In addition, my child's blood pressure will be taken. During this visit, my child will sit in a chair in front of a small table. My child will be play a game in which monkey's will be placed in trees according to a few rules. In addition, my child will also be asked to play with blocks, put puzzles together, and be asked questions to test their general knowledge, comprehension, and vocabulary. My child will also be presented with different patterns or shapes and be asked to fill in the missing piece. In addition, my child will be shown a series of pictures and

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be asked which two go together. My child will also be shown a series of symbols and be asked to find the two that match. My child will play a game and try to figure out what the investigator is thinking of based on the clues given. My child will also be shown a series of pictures and be asked what is missing. The investigators will describe these tests to me in detail before each is started. The visit will be videotaped and I will be with my child the whole time. I will be asked some questions about events in my child's life. This visit will take approximately 2 hours.

RISKS
There are no known risks from any of the tasks that my child will be asked to do. Some of the tasks may be tiring and my child may not like wearing the cap, but the investigators will not continue with a test if the child is not performing at his/her best because he/she is tired or excessively bothered by wearing the cap.

NEW FINDINGS STATEMENT
The study will continue to follow the development of my child between 2 and 6 years of age. I will be informed if any significant new findings develop during the course of the study that may affect my willingness to participate or to allow my child to participate in this study.
I may request to know results when the study is complete.

BENEFITS
My child will not benefit from participating in this study. It is hoped that additional information gained in this research study may be useful in the growth and development of infants.

ALTERNATIVES
My child does not have to participate in this research study.

COSTS
I will not incur any costs because of my child's participation.

PAYMENT TO SUBJECTS
I will receive a check for $100 at each visit to the University of Kansas Medical Center to cover the costs of transportation and to partially compensate me for my time required to participate in the study. If I do not have enough money to come for the visit, I may ask the investigators to pay for a cab to and from the appointment andI will be given the $100 check, however, the investigators will have to deduct the cost of the cab from my next check. There will be 8 regularly scheduled visits in 4 years. If an additional visit is required because my infant is unable to complete all of the testing at 6 years of age, I will receive an additional payment of $50 for another visit.

My name, address, social security number, and the title of this study will be given to the KUMC Research Institute. This is done so that the Research Institute can write a check for study payments. Payments are taxable income.

DISCLOSURE OF FINANCIAL INTERESTS
The principal investigator has been paid as a consultant and for program presentation on DHA for Mead Johnson Nutritionals (the sponsor). The University of Kansas Medical Center

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Conflict of Interest Committee monitors this research project to make it less likely that these financial interests inappropriately influence how the study is conducted. However, you should make your own decision about whether these financial interests affect your decision to participate. If you have any questions about this financial relationship, you may discuss them with the investigator or with the Research Compliance division at 913-588-5492.

INSTITUTIONAL DISCLAIMER STATEMENT

If you believe you have been injured as a result of participating in research at Kansas University Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Compensation to persons who are injured as a result of participating in research at KUMC may be available, under certain conditions, as determined by state law or the Kansas Tort Claims Act.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

Names of subjects or information identifying subjects will not be released without written permission unless required by law. Study data will be shared with the sponsor, but I will not be identified. Videotapes of my baby when he/she is looking at pictures and playing with toys will be used only by the investigators and their students. The videotapes will be secured under lock and key like all of other information that could be linked directly to my child. The videotape of my child will not be shown without specific permission from me and even then would not identify my child by name. The videotapes will be destroyed after all of the study data are collected and analyzed. Because study will continue for 4 more years and enrollment occurred during 2 years, the investigators may keep a copy of my child's videotape for as long as 8 years. Efforts will be made to keep my and my child's personal information confidential. Researchers cannot guarantee absolute confidentiality. If the results of this study are published or presented in public, information that identifies my baby will be removed.

The privacy of my and my child's health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). If I choose to allow my child to participate in this study, I will be asked to give permission for researchers to use and disclose my and my baby's health information that is relevant to the study.

Because this is a continuation of an existing study, researchers already have some health information about my child from his/her medical record with consent. They will not obtain any other information except the information that they conduct as shared in the Procedures section. My baby's study-related health information will be used at KU Medical Center by Dr. Carlson, members of the research team, the KU Hospital Medical Record Department, the KUMC Research Institute and officials at KUMC that oversee research, including the KUMC Human Subjects Committee, and other committees and offices that review and monitor research studies.

Dr. Carlson and her team may share information about me and my baby with representatives of Mead Johnson (the sponsor of the study), the U.S. Food and Drug Administration (FDA), and U.S. agencies that govern human research (if and when regulatory compliance issues

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arise). My and my child's information may be shared in order to analyze and confirm the results of the study.

Some of the persons or groups that receive my and my baby's study information may not be required to comply with HIPAA privacy laws. My and my child's information may lose its federal protection if those persons or groups disclose it.

Permission granted on this date to use and disclose my health information remains in effect indefinitely. By signing this form I give permission for the use and disclosure of my and my child's information for purposes of the study at any time in the future.

QUESTIONS

I have read the information in this form. Dr. Carlson or her associates have answered my question(s) to my satisfaction. I know if I have any more questions after signing this I may contact Dr. Carlson or one of her associates at (913) 588-5359. If I have any questions about my child's rights as a research subject, I may call (913) 588-1240 or write the Human Subjects Committee, University of Kansas Medical Center, 3901 Rainbow Blvd. MSN 1032, Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

My and my child's participation in this study is voluntary and that the choice not to participate or to quit at any time can be made without penalty or loss of benefits. Not participating or quitting will have no effect upon the medical care of treatment my child receives now or in the future at the University of Kansas Medical center. The entire study may be discontinued for any reason without my consent by the investigator conducting the study or by the sponsor of the study. My child's participation can be discontinued by the investigator if I do not come for scheduled visits.

You have a right to change your mind about allowing the research team to have access to your healthy information. To cancel your permission you must send a written request to Dr. Carlson at the University of Kansas Medical Center, Dept. of Dietetics and Nutrition, Mail Stop 4013, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study and the researchers will stop collecting information about you. The researchers and the sponsor may continue to use and share information that was gathered before your cancellation.

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CONSENT

Dr. Carlson or her associates have given me information about this research study. They have explained what will be done and how long it will take. They explained the inconvenience, discomfort and risks that may be experienced during this study.

By signing this form, I give my permission for my child to continue with followup for an additional 8 visits (at 6 ages) between 2 and 6 years of age. If I choose not to sign this form, my child and I will not be able to participate in the study.

I voluntarily consent to allow my child and I to participate in this research study. I have read the information in this form and have had an opportunity to ask questions and have them answered. ***I will be given a copy of the signed form to keep for my records.***

_____
Type/Print Subject's Name

_____ _____ _____
Signature of Subject Time Date

_____
Type/Print Name of Witness

_____ _____
Signature of Witness Date

_____
Type/Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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APPENDIX C

Subject Demographic Data Collection Form

INVESTIGATOR PROTOCOL RANDOM CODE DATE

CARLSON HSC #10205

DEMOGRAPHICS

Maternal Education

Paternal Education

Does anyone living in the child's home smoke?

☐ No ☐ Yes If yes, how many people smoke & how many ppd? _____

List any maternal allergies:

_____

Including the child enrolled in this study, how many children 13 years of age or younger live in your house?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 or more

Do any pets live in the child's home?

☐ No ☐ Yes If yes, how many pets? _____
What kind?
_____

Do you take your child to a daycare (facility or homecare) with other infants and children?

☐ No

☐ Yes, with 1 to 5 children

☐ Yes, with 6 to 10 children

☐ Yes, with more than 10 children

APPENDIX D

Subject Anthropometric Data Collection Form

ANTHROPOMETRICS

2 Year Visit MO DA YEAR	Weight		g
	Length		cm
	Head circumference		cm
2.5 Year Visit MO DA YEAR	Weight		g
	Length		cm
	Head circumference		cm
3 Year Visit MO DA YEAR	Weight		g
	Length		cm
	Head circumference		cm
3.5 Year Visit MO DA YEAR	Weight		g
	Length		cm
	Head circumference		cm
4 Year Visit MO DA YEAR	Weight		g
	Length		cm
	Head circumference		cm

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ANTHROPOMETRICS PAGE 2

4.5 Year Visit MO DA YEAR	Weight	g
	Length	cm
	Head circumference	cm
5 Year Visit MO DA YEAR	Weight	g
	Length	cm
	Head circumference	cm
5.5 Year Visit MO DA YEAR	Weight	g
	Length	cm
	Head circumference	cm
6 Year Visit MO DA YEAR	Weight	g
	Length	cm
	Head circumference	cm

APPENDIX E

24-Hour Dietary Recall Form

24-Hour Dietary Recall Form

Visit:_____

Random #_____ Date of Intake:_____ DOB:_____ EDC:_____

Time	Food/Beverage	Ingredients/Preparation	Amount

Intake: Typical More than Usual Less than Usual Why? _____

_____

Recall: Reliable Unable to recall meals? Unreliable for other reasons? Why? _____

_____

Vitamin/Mineral/Supplement Use? _____

Home / Daycare / Babysitter Number of people responsible for feeding _____

Interviewer Initials: _____

APPENDIX F

NDS-R Food Groups Output

Subgroup Name	Includes/Examples	Excludes/Examples	Serving Size
Citrus Juice	1. 100% citrus juice (sweetened or unsweetened orange, grapefruit, tangerine) 2. Frozen concentrate	1. Drinks with < 100% juice 2. Fruit juice bars are not 100% juice	4 fluid ounces
Fruit Juice excluding Citrus Juice	1. 100% juice (sweetened or unsweetened) 2. Frozen concentrate	1. Drinks with < 100% juice 2. Cranberry drinks are not 100% juice 3. Fruit juice bars are not 100% juice 4. Fruit nectars are not 100% juice	4 fluid ounces
Citrus Fruit	1. Fresh, cooked and canned citrus fruits (e.g., oranges, grapefruit, tangerines, lemons) 2. Citrus fruit in recipes (e.g., salads, Jell-O)	1. Fruits other than citrus fruits 2. Jam, jelly, marmalade	1. Fresh, frozen, canned, or cooked = ½ cup chopped or default form 2. 1 medium piece when appropriate (e.g., 1 medium orange) 3. ½ fresh grapefruit 4. Dried = ¼ cup
Fruit excluding Citrus Fruit	1. Fresh, frozen, cooked, canned, and dried 2. Fruit in recipes (e.g., salads, Jell-O, caramel apple) 3. Fruit relish, or salsa 4. Fruit in cereal if actual fruit pieces (e.g., raisins)	1. Citrus fruits (e.g., oranges, grapefruit, tangerines, lemons) 2. Fruit in: Baked goods, desserts, Pies, Trail mix, candy (e.g., chocolate covered raisins), Granola bars, Ice cream 3. Maraschino cherries 4. Fruit leather or fruit roll-ups 5. Jam, jelly, marmalade 6. Fruit relishes if "pickled"	1. Fresh, frozen, canned, or cooked = ½ cup chopped or default form 2. 1 medium piece when appropriate (e.g., 1 medium banana) 3. Dried = ¼ cup
Avocado and Similar			½ cup chopped or default form
Fried Fruits 1	1. Fried bananas 2. Fried apples		½ cup chopped or default form
Fruit-based Savory Snack	1. Apple chips 2. Banana chips		1 ounce
Dark-green Vegetables	1. Raw, cooked, and canned 2. Dark-green vegetables (e.g., broccoli, spinach, romaine, collards)	Fried and/or breaded vegetables (e.g., breaded broccoli)	1. Raw, cooked, or canned = ½ cup chopped or default form 2. Raw leafy

	3. Vegetable in recipes (e.g., stew, soup)		vegetables = 1 cup
Deep-yellow Vegetables	1. Raw, cooked, and canned 2. Deep-yellow vegetables (e.g., carrots, pumpkin, sweet potatoes, winter squash) 3. Vegetable in recipes (e.g., stew, soup)	Fried and/or breaded vegetables (e.g., breaded squash)	Raw, cooked, or canned = ½ cup chopped or default form
Tomato	1. Raw, cooked and canned tomato 2. Salsa 3. Tomato sauce 4. Spaghetti sauce 5. Tomato-based sauce 6. Tomato puree 7. Tomato paste 8. Tomato in recipes (e.g., stew, soup)	1. Catsup 2. Steak sauce 3. Cocktail sauce	1. ½ cup chopped or default form 2. Tomato sauce = ½ cup 3. Tomato puree = ¼ cup 4. Tomato paste = ¼ cup
White Potatoes	1. Baked, boiled, and canned white potatoes 2. Potatoes in recipes (e.g., stew)		1. ½ cup chopped or default form 2. 1 medium baked potato
Fried Potatoes	1. French fries 2. Hash browns 3. Pan fried potatoes 4. Potato tots	Potato chips	1. ½ cup chopped or default form 2. French fries = 70 g
Other Starchy Vegetables	1. Raw, cooked, and canned 2. Starchy vegetables (e.g., cassava, corn, green peas, jicama) 3. Vegetable in recipes (e.g., stew, soup) 4. Vegetables with more starch than peas	1. Fried and/or breaded vegetables 2. Mixed vegetables with a starchy vegetable	1. Raw, cooked, or canned = ½ cup chopped or default form 2. Raw leafy vegetables = 1 cup
Legumes (cooked dried beans)	1. Dried beans 2. Mature lima beans 3. Refried beans 4. Beans in sauce (e.g., pork and beans) 5. Beans in recipes (e.g., stew, soup)	1. Soy-based desserts (e.g., Tofutti) 2. TVP, products with TVP (e.g., veggie burgers, meat with TVP) 3. Soy nuts 4. Tofu 5. Tempeh	1. Cooked dry beans = ½ cup 2. Refried beans = ½ cup 3. Beans in sauce = ½ cup

Other Vegetables	1. Raw, cooked and canned 2. Vegetable in recipes (e.g., stew, soup) 3. Vegetable relishes 4. Mixed vegetables from other categories (e.g., peas and carrots; corn, peas, lima beans)	1. Olives 2. Pickles and pickled vegetables (e.g., sauerkraut)	1. Raw, cooked, or canned = ½ cup chopped or default form 2. Raw leafy vegetables = 1 cup
Fried Vegetables	1. Fried and/or breaded vegetables (e.g., breaded broccoli, mushrooms, eggplant) 2. Onion rings		½ cup chopped or default form
Vegetable Juice	100% juice	1. Drinks with < 100% juice 2. Clamato juice is not 100% juice	4 fluid ounces

APPENDIX G

Excluded Dietary Recalls

Unable to recall one or more meals: 95 total
Subject 74 at 12 months
Subject 124 at 12 months

Subject 2 at 18 months
Subject 46 at 18 months
Subject 60 at 18 months
Subject 84 at 18 months
Subject 89 at 18 months
Subject 91 at 18 months
Subject 125 at 18 months

Subject 5 at 2 years
Subject 24 at 2 years
Subject 35 at 2 years
Subject 43 at 2 years
Subject 62 at 2 years
Subject 102 at 2 years
Subject 103 at 2 years

Subject 9 at 2.5 years
Subject 139 at 2.5 years

Subject 103 at 3 years

Subject 46 at 3.5 years
Subject 108 at 3.5 years
Subject 127 at 3.5 years

Subject 97 at 4 years
Subject 102 at 4 years
Subject 135 at 4 years
Subject 148 at 4 years
Subject 154 at 4 years

Subject 32 at 4.5 years
Subject 48 at 4.5 years
Subject 102 at 4.5 years
Subject 110 at 4.5 years
Subject 112 at 4.5 years
Subject 120 at 4.5 years
Subject 131 at 4.5 years

Subject 35 at 5 years
Subject 48 at 5 years
Subject 75 at 5 years

Subject 77 at 5 years
Subject 88 at 5 years
Subject 100 at 5 years
Subject 112 at 5 years
Subject 113 at 5 years
Subject 120 at 5 years
Subject 124 at 5 years
Subject 131 at 5 years
Subject 134 at 5 years

Over reporting (>200 kcals/kg): 23 total
Subject 59 at 12 months
Subject 95 at 12 months

Subject 4 at 18 months
Subject 19 at 18 months
Subject 98 at 18 months
Subject 120 at 18 months
Subject 121 at 18 months
Subject 147 at 18 months

Subject 88 at 2 years
Subject 120 at 2 years
Subject 143 at 2 years
Subject 147 at 2 years

Subject 97 at 2.5 years
Subject 108 at 2.5 years

Underreporting (<40 kcal/kg): 54 total
Subject 42 at 12 months
Subject 118 at 12 months

Subject 87 at 18 months
Subject 89 at 18 months

Subject 35 at 2 years

Subject 9 at 4 years
Subject 46 at 4 years
Subject 97 at 4 years

Subject 9 at 4.5 years
Subject 32 at 4.5 years
Subject 48 at 4.5 years
Subject 62 at 4.5 years

Subject 110 at 4.5 years
Subject 112 at 4.5 years

Subject 35 at 5 years
Subject 77 at 5 years
Subject 97 at 5 years
Subject 112 at 5 years
Subject 134 at 5 years